SUBCHAPTER B—MEDICARE PROGRAM

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart A—[Reserved]

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Subpart A—[Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862, and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) HCFA uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) HCFA may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with HCFA to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for ''premarket approval'' and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at §411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at §411.15(o) of this chapter, the FDA notifies the sponsor and HCFA and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because HCFA determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises because of the use of a noncovered device or from the furnishing of related noncovered services.

§ 405.209 Payment for a non-experimental/investigational (Category B) device.

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all HCFA administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an

FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by HCFA only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor HCFA's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both HCFA and the sponsor of its decision.

(c) *Request to HCFA.* If the FDA does not agree to recategorize the device, the sponsor may seek review from HCFA. A device sponsor must submit its request in writing to HCFA. HCFA obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. HCFA reviews all material submitted by the sponsor and the FDA's recommendation. HCFA reviews only information in the FDA record to determine whether to change the categorization of the device. HCFA issues a written decision and notifies the sponsor of the IDE and the FDA.

§ 405.215 Confidential commercial and trade secret information.

To the extent that HCFA relies on confidential commercial or trade secret information in any judicial proceeding, HCFA will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Health Care Financing Administration that more than the correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.350 was amended by revising the introductory paragraph, effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.356, where:

* * * * *

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended by 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery

would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault shall be deemed to be against equity and good conscience if the determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual. (See §§ 405.330–405.332 for conditions under which payment may be made for items or services furnished after October 30, 1972 which are noncovered by reasons of § 405.310 (g) and (k).)

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.356 was revised, effective Oct. 21, 1996. For the convenience of the user the superseded text is set forth as follows:

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of 20 CFR 404.506–404.509, 404.510a, and 404.512.

[35 FR 6321, Apr. 18, 1970. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or recovery of the overpayment is to be effected (see § 405.358).

[61 FR 49271, Sept. 19, 1996]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.357 was added, effective Oct. 21, 1996.

§ 405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

(a) Who is without fault, and

(b) Adjustment or recovery would either:

(1) Defeat the purposes of title II or title XVIII of the Act, or

(2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

EFFECTIVE DATE NOTE: At 61 FR 49271, Sept. 19, 1996, § 405.358 was added, effective Oct. 21, 1996.

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355), or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Suspension of Medicare payments to providers and suppliers.

(a) Medicare payments to providers and suppliers, as authorized under this chapter (excluding payments to beneficiaries), may be suspended, in whole or in part, by an intermediary or a carrier when—

(1) The intermediary or carrier has determined that the provider or other supplier to whom such payments are to be made has been overpaid under title XVIII of the Social Security Act, or

(2) The intermediary or carrier has reliable evidence, although additional

evidence may be needed for a determination, that such overpayment exists or that the payments to be made may not be correct.

(b) A suspension shall be put into effect only after the provisions in §§ 405.371 and 405.372 have been complied with and the intermediary or carrier has determined that the suspension of payments, in whole or in part, is needed to protect the program against financial loss. The provisions of this section and §§ 405.371–405.373 shall be effective on May 27, 1972.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6647, Mar. 2, 1988]

§ 405.371 Proceeding for suspension.

(a) *General.* Whenever the intermediary or carrier has determined that a suspension of payments under § 405.370 should be put into effect with respect to a provider of services or other supplier of services, the intermediary or carrier shall notify the provider or other supplier of its intention to suspend payments, in whole or in part, and the reasons for making such suspension. The provider or other supplier will be given the opportunity to submit any statement (including any pertinent evidence) as to why the suspension shall not be put into effect and shall have 15 days following the date of notification to submit such statement, unless the intermediary or carrier for good cause imposes a shorter period. The intermediary or carrier may, for good cause shown, extend the time within which the statement may be submitted. If no statement is received within the 15-day period or such other period as specified in the notice, the suspension shall go into effect.

(b) *Fraud or misrepresentation.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier has reliable evidence that the circumstances giving rise to the need for a suspension of payments involves fraud or willful misrepresentation. Instead, the intermediary or carrier may suspend payments without first notifying the provider or other supplier of an intention to suspend payments. The provider or other supplier will be notified of such suspension and the reasons for taking such action.

(c) *Notice of amount of program reimbursement.* The provisions of paragraph (a) of this section shall not apply where the intermediary, after furnishing a provider a written notice of the amount of program reimbursement pursuant to § 405.1803, suspends payment under paragraph (b) of such § 405.1803.

(d) *Failure to furnish information requested.* The provisions of paragraph (a) of this section shall not apply where the intermediary or carrier suspends payments to a provider or other supplier of services because such provider or supplier of services has failed to submit evidence requested by such intermediary or carrier which is needed to determine the amounts due such provider or supplier under the program (sections 1815 and 1833(e) of the Act).

[37 FR 10723, May 27, 1972, as amended at 41 FR 52050, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.372 Submission of evidence and notification of administrative determination to suspend.

When pursuant to § 405.371(a) the provider or other supplier submits a statement, the intermediary or carrier shall consider such statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and make a determination as to whether the facts justify a suspension authorized by § 405.373. If the intermediary or carrier determines that a suspension should go into effect, written notice of such determination will be sent to the provider or other supplier. Such notice will contain specific findings on the conditions upon which the suspension was based, and an explanatory statement for the final decision.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.373 Subsequent action by intermediary or carrier.

(a) Where a suspension is put into effect by reason of § 405.370(a)(1), such suspension shall remain in effect until whichever of the following first occurs:

(1) The overpayment is liquidated, (2) the intermediary or carrier enters into

an agreement with the provider or other supplier for liquidation of the overpayment, or (3) the intermediary or carrier, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment; except that the intermediary or carrier may at any time adjust such suspension for an appropriate period if it determines that continuation of the suspension would cause irreparable harm to the provider or other supplier.

(b) Where the suspension is put into effect by reason of §405.370(a)(2), the intermediary or carrier will take timely action after such suspension to obtain such additional evidence it may need to make a determination as to whether an overpayment exists or the payments may be made (i.e., evidence from the records of the provider or other supplier of services). All reasonable efforts will be made by the intermediary or carrier to expedite such determinations. As soon as such determination is made, the provider or other supplier will be informed and, where appropriate such suspension will be rescinded or adjusted to take into account such determination. If such suspension is not rescinded, it shall remain in effect as specified in paragraph (a) of this section.

(c) The provisions of this section shall not apply where the intermediary or carrier, in suspending payments pursuant to §405.370, has reliable evidence that the circumstances giving rise to such suspension involve fraud or serious misrepresentation.

[37 FR 10723, May 27, 1972. Redesignated at 42 FR 52826, Sept. 30, 1977]

§405.374 Collection and compromise of claims for overpayments.

(a) *Scope.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider, physician, or other supplier of services under the Medicare program. It is adopted pursuant to the Federal Claims Collection Act (31 U.S.C. 951–953). Collection and compromise of claims against Medicare beneficiaries is explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Health Care Financing Administration (HCFA) if;

(1) The claim does not exceed $100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension.* Collection action may be suspended for either of the

following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, HCFA will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that HCFA has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by HCFA. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by HCFA.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by HCFA under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 56998, Dec. 2, 1992]

§405.375 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers specified in paragraph (b) of this section that have not arranged to repay Medicaid overpayments as determined by the Medicaid agency or have failed to provide information necessary to determine the amount of overpayment.

(b) *When withholding may be used.* HCFA may withhold Medicare payments to recover Medicaid overpayments that a Medicaid agency has been unable to collect, if—

(1) The Medicaid agency has followed the procedure specified in §447.31 of this chapter, and

(2) The institution or person is one described in paragraphs (c)(1) or (c)(2) of this section.

(c) *Institutions or persons affected*— (1) HCFA may withhold Medicare payments to recover Medicaid overpayments with respect to any of the following entities that has or had in effect, an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(i) An institutional provider that has in effect an agreement under section 1866 of the Act.

(ii) A physician or supplier who has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act.

(2) HCFA may withhold Medicare payment from an institution or person specified in paragraph (c)(1) of this section that—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(d) *Amount to be withheld*—(1) HCFA will contact the appropriate intermediary or carrier to determine the amount of Medicare payment to which the institution or person is entitled.

(2) HCFA may require the intermediary or carrier to withhold Medicare payments to the institution or person by the lesser of the following amounts;

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding*—If HCFA intends to withhold payments under this section, HCFA will notify by certified mail, return receipt requested, the institution or person and the intermediary or carrier responsible for making Medicare payment to the institution or person of the intention to withhold Medicare payments. The notice will include:

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* HCFA will terminate the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person makes an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* HCFA will return to the Medicaid agency amounts withheld under this section to offset the agency's Medicaid overpayment.

[50 FR 19688, May 10, 1985]

§ 405.376 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d) and 1833(j) of the common law and Act, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) HCFA will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Interest will accrue from the date of the final determination as defined in paragraph (c) of this section, and will either be charged on the overpayment balance or paid on the underpayment balance for each 30-day period that payment is delayed. (Periods of less than 30 days will be treated as a full 30-day period, and the 30-day interest charge will be applied to any balance.)

(c) *Definition of final determination.* (1) For purposes of this section, any of the following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that is, primarily under part B), one of the following determinations is issued—

(A) A written determination that an overpayment exists and a written demand for payment;

(B) A written determination of an underpayment; or

(C) An Administrative Law Judge (ALJ) decision that reduces the amount of an overpayment below the amount that HCFA has already collected.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§ 417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under § 413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due HCFA, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal, interest accrues from the date of final determination as specified in this subsection.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due HCFA but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due HCFA, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted

for good cause, as specified in §413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) HCFA may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under §413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(i) *Nonallowable cost.* As specified in §§412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See §413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, ''provider'' includes all entities eligible to

receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—[Reserved]

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health services covered by the Medicare program. Section 1861(v) sets forth the general authority under which HCFA may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term ''covered osteoporosis drug.'' Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment

under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the ''reasonable charge'' for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of ''reasonable cost'' (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, Federally qualified health centers and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995]

§ 405.502 Criteria for determining reasonable charges.

(a) Criteria. The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges adjusted to reflect economic changes as provided under § 405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by HCFA or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in § 405.580 in teaching and non-

teaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which HCFA has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under § 415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Health Care Financing Administration, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Health Care Financing Administration. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under §416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with §405.503, the prevailing charges applicable to these services in accordance with §405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of reasonable charges in special circumstances: General.* HCFA or a carrier may establish special reasonable charge limits for a category of service if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly deficient charge. The limit is either a specific dollar amount, or is based on a special method to be used in determining the reasonable charge.

(1) *Determination of excessive or deficient charges.* HCFA or a carrier may make a determination that the standard rules for calculating reasonable charges set forth in this subpart result in grossly deficient or excessive charges. HCFA's determination may apply to the services of any supplier; however, a carrier's determination may apply only to nonphysician services. Examples of the circumstances which may result in grossly deficient or excessive charges include, but are not limited to the following:

(i) The marketplace is not competitive. This includes circumstances in which the marketplace for a service is not truly competitive because a limited number of physicians perform the service.

(ii) Medicare and Medicaid are the sole or primary sources of payment for a service.

(iii) The charges involve the use of new technology for which an extensive charge history does not exist.

(iv) The charges do not reflect changing technology, increased facility with that technology, or changes in acquisition, production or supplier costs.

(v) The prevailing charges for a service in a particular locality are significantly in excess of or below prevailing charges in other comparable localities, taking into account the relative costs of furnishing the services in the different localities.

(vi) Charges are grossly lower than or in excess of acquisition or production costs.

(vii) There have been increases in charges for a service that cannot be explained by inflation or technology.

(viii) The prevailing charges for a service are substantially higher or lower than the payments made for the service by other purchasers in the same locality.

(2) *Establishing a limit.* In establishing a limit, HCFA or a carrier considers the available information that is relevant to the category of service and establishes a reasonable charge that is realistic and equitable. The factors to be considered in establishing a specific dollar amount or special method may include the following:

(i) *Price markup.* This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of service. If information on a particular category of service is not available, HCFA or a carrier may consider the markup on similar services and information on general industry pricing trends.

(ii) *Differences in charges.* HCFA or a carrier may consider the differences in charges to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* HCFA or a carrier may consider resources (overhead, time, acquisition costs, production costs, complexity, etc.) required to produce a service or a product.

(iv) *Utilization.* HCFA or a carrier may impute a reasonable rate of use for a category of service and consider unit costs based on efficient utilization.

(v) Charges in other localities.

(vi) Other relevant factors.

(3) *Notification of limits*—(i) *National limits.* When HCFA makes a determination regarding nonphysicians' services under this section, it publishes in the FEDERAL REGISTER proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(ii) *Carrier level limits.* After September 9, 1988, a carrier proposing to establish a generally applicable special reasonable charge limit must inform the affected suppliers and State Medicaid agencies of the factors considered in establishing the limit as described in paragraphs (g) (1) and (2) of this section and solicit comments. After evaluating the comments received, the carrier must inform the affected suppliers and State Medicaid agencies of any final limit established. The limit is effective for services furnished no fewer than 30 days after the date of the carrier's notification.

(h) *Determination of reasonable charges in special circumstances: Physician services.* In establishing special reasonable charge limits for a category of physician services, HCFA applies the general rules under paragraphs (g) (1) and (2) of this section and the following special rules:

(1) *Potential impact of special limit.* In determining whether to set a special reasonable charge limit for a category of physician service, HCFA considers the potential impact on quality, access, beneficiary liability, assignment rates, reasonable charge reductions on unassigned claims, and participation rates of physicians.

(2) *Physician consultation.* Before making a determination that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, HCFA consults with representatives of the physicians likely to be affected by any change in the reasonable charge.

(3) *Special limits based on comparison of charges in different localities.* HCFA

takes into account differences in practice costs before basing a special limit on the comparison of prevailing charges in different localities.

(4) *Factors considered in establishing a special limit.* (i) In establishing the specific dollar amount or special method under paragraph (g)(2) of this section, HCFA takes into account regional differences in fees unless there is substantial economic justification, as described in the proposed and final notices required under paragraphs (h)(5)(i) and (ii) of this section, for a uniform fee or a uniform payment limit.

(ii) In determining that a charge is not inherently reasonable by reason of its grossly excessive or deficient amount, and in establishing the specific dollar amount or special method under paragraphs (g) (1) and (2) of this section, HCFA may compare the charge to the—

(A) Resource costs (that is, factors such as the time required to provide a procedure, including pre-procedure evaluation and post-procedure follow-up; the complexity of the procedure; the training required to perform the procedure; and the risk involved in the procedure) for related services;

(B) Resource costs for the service over a period of time;

(C) Charges for the service in different geographic areas after accounting for differences in practice costs;

(D) Payments for a service allowed under Medicare Part B and by other payors; and

(E) Other relevant factors.

(5) *Publication of national limits.* When HCFA makes a determination under this section, it publishes in the FEDERAL REGISTER proposed and final notices of a special reasonable charge limit before the limit is adopted. The notice sets forth in the FEDERAL REGISTER the criteria and circumstances, if any, under which a carrier may grant an exception to the limit.

(i) *Proposed notice.* The proposed notice—

(A) Specifies the proposed charge or methodology to be established with respect to a service;

(B) Explains the factors and data that HCFA took into account in determining the charge or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(C) Explains the potential impacts of a limit on physicians' services as described in paragraph (h)(1) of this section; and

(D) Allows no less than 60 days for public comment on the proposal.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that HCFA took into consideration, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments and any comments made by the Physician Payment Review Commission.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1))

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term ''customary charges'' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law

for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a ''customary charge'' for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's ''customary'' charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by HCFA; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to HCFA, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen

year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent ((.40×112)+(.60)×110)=110.8) above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than $1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to

HCFA, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992*—(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights [1,2] (percent)	Price proxy [3]
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm.[4]
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm.[4]
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees.[4]
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar.[4]
b. Office Expense	10.3	CPI–U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI–U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	HCFA survey of change in average liability premiums for $100,000/$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI–U, private transportation.
(2) Other	5.5	CPI–U, all items less food and energy.

[1] Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990.* Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, ''Practice Expenses Take the Leap of the Decade,'' *Medical Economics,* November 12, 1990; and HCFA, OACT special study.

[2] Due to rounding, weights may not sum to 100.0%

[3] All price proxies are for *annual* percent changes for the 12 months ending June 30th.

[4] Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, HCFA publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

''Locality'' is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to ''trade areas.'' Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* ''Comparable circumstances,'' as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Health Care Financing Administration. When the pertinent information has been reported, the Health Care Financing Administration will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of HCFA generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from HCFA as follows:

(1) *For items or services furnished on or before December 31, 1986.*

(i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.*

(i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating

the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§ 405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Health Care Financing Administration with all pertinent data and information for approval before the revision is implemented. The Health Care Financing Administration will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Health Care Financing Administration will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians' services for services which are identified by a single element of terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 10298, Mar. 4, 1994]

§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and

deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs that are not paid on a cost or prospective payment basis.

(a) *Applicability.* Payment for a drug that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies includes a drug furnished incident to a physician's service and a drug furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter.

(b) *Methodology.* Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

(c) *Multiple-Source drugs.* For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

[56 FR 59621, Nov. 25, 1991]

§ 405.534 Limitation on payment for screening mammography services.

(a) *Basis and scope.* This section implements section 1834(c) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994]

§ 405.535 Special rules for nonparticipating physicians and suppliers furnishing screening mammography services.

If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b)(3) of this chapter.

[59 FR 49833, Sept. 30, 1994]

Subpart F—[Reserved]

Subpart G—Reconsiderations and Appeals Under Medicare Part A

AUTHORITY: Secs. 1102, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c–4, 1395ff(b), 1395hh, 1395ii, and 1395pp).

SOURCE: 37 FR 5814, Mar. 22, 1972, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.701 Basis, purpose and definitions.

(a) This subpart implements section 1869 of the Social Security Act. Section 1869(a) provides that the Secretary will make determinations about the following matters, and section 1869(b) provides for a hearing for an individual who is dissatisfied with the Secretary's determination as to:

(1) Whether the individual is entitled to hospital insurance (part A) or supplementary medical insurance (part B) under title XVIII of the Act; or

(2) The amount payable under hospital insurance.

(b) This subpart establishes the procedures governing initial determinations, reconsidered determinations, hearings, and final agency review, and the reopening of determinations and decisions that are applicable to matters arising under paragraph (a) of this section.

(c) Subparts J and R of 20 CFR part 404 (dealing with determinations, the administrative review process and representation of parties) are also applicable to matters arising under paragraph (a) of this section, except to the extent that specific provisions are contained in this subpart.

(d) *Definitions.* As used in subpart G of this part, the term—

Appellant designates the beneficiary, provider or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part A. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for a hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more provider appellants to meet the minimum amount in controversy needed for a hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

[55 FR 11020, Mar. 26, 1990, as amended at 59 FR 12181, Mar. 16, 1994]

§ 405.702 Notice of initial determination.

After a request for payment under part A of title XVIII of the Act is filed with the intermediary by or on behalf of the individual who received inpatient hospital services, extended care services, or home health services, and the intermediary has ascertained whether the items and services furnished are covered under part A of title XVIII, and where appropriate, ascertained and made payment of amounts due or has ascertained that no payments were due, the individual will be notified in writing of the initial determination in his case. In addition, if the items or services furnished such individual are not covered under part A of title XVIII by reason of §411.15(g) or §411.15(k) and payment may not be made for such items or services under §411.400 only because the requirements of §411.400(a)(2) are not met, the provider of services which furnished such items or services will be notified in writing of the initial determination in such individual's case. These notices shall be mailed to the individual and the provider of services at their last known addresses and shall state in detail the basis for the determination. Such written notices shall also inform the individual and the provider of services of their right to reconsideration of the determination if they are dissatisfied with the determination.

[55 FR 11020, Mar. 26, 1990]

§ 405.704 Actions which are initial determinations.

(a) *Applications and entitlement of individuals.* An initial determination with respect to an individual includes the following—

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance;

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA will specify in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence);

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance;

(4) A denial of a request for cancellation of a ''request for withdrawal''; and

(5) A determination as to whether an individual, previously determined to be

entitled to hospital or supplementary medical insurance, is no longer entitled to such benefits, including a determination based on nonpayment of premiums.

(b) *Requests for payment by or on behalf of individuals.* An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under part A of Medicare, including a determination with respect to:

(1) The coverage of items and services furnished;

(2) The amount of an applicable deductible;

(3) The application of the coinsurance feature;

(4) The number of days of inpatient hospital benefits utilized during a spell of illness or for purposes of the inpatient psychiatric hospital 190-day lifetime maximum;

(5) The number of days of the 60-day lifetime reserve utilized for inpatient hospital coverage;

(6) The number of days of posthospital extended care benefits utilized;

(7) The number of home health visits utilized;

(8) The physician certification requirement;

(9) The request for payment requirement;

(10) The beginning and ending of a spell of illness, including a determination made under the presumptions established under §409.60(c)(2) of this chapter, as specified in §409.60(c)(4) of this chapter.

(11) The medical necessity of services (See parts 466 and 473 of this chapter for provisions pertaining to initial and reconsidered determinations made by a PRO);

(12) When services are excluded from coverage as custodial care (§411.15(g)) or as not reasonable and necessary (§411.15(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see §411.402);

(13) Any other issues having a present or potential effect on the amount of benefits to be paid under part A of Medicare, including a determination as to whether there has been an overpayment or underpayment of benefits paid under part A, and if so, the amount thereof; and

(14) Whether a waiver of adjustment or recovery under sections 1870 (b) and (c) of the Act is appropriate when an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) has been made with respect to an individual.

(c) *Initial determination with respect to a provider of services.* An initial determination with respect to a provider of services shall be a determination made on the basis of a request for payment filed by the provider under part A of Medicare on behalf of an individual who was furnished items or services by the provider, but only if the determination involves the following:

(1) A finding by the intermediary that such items or services are not covered by reason of §411.15(g) or §411.15(k); and

(2) A finding by the intermediary that either such individual or such provider of services, or both, knew or could reasonably have been expected to know that such items or services were excluded from coverage under the program.

[55 FR 11020, Mar. 26, 1990]

§ 405.705 Actions which are not initial determinations.

An initial determination under Part A of Medicare does not include determinations relating to:

(a) The reasonable cost of items or services furnished under Part A of Medicare;

(b) Whether an institution or agency meets the conditions for participation in the program;

(c) Whether an individual is qualified for use of the expedited appeals process as provided in §405.718;

(d) An action regarding compromise of a claim arising under the Medicare program, or termination or suspension of collection action on such a claim under the Federal Claims Collection Act of 1966 (31 U.S.C. 951–953). See 20 CFR 404.515 for overpayment claims

against an individual, § 405.374 for overpayment claims against a provider, physician or other supplier, and § 408.110 for claims concerning unpaid Medicare premiums;

(e) The transfer or discharge of residents of skilled nursing facilities in accordance with § 483.12 of this chapter; or

(f) The preadmission screening and annual resident review processes required by part 483 subparts C and E of this chapter.

[45 FR 73932, Nov. 7, 1980; 46 FR 24565, May 1, 1981, as amended at 52 FR 22454, June 12, 1987; 52 FR 48123, Dec. 18, 1987; 57 FR 56504, Nov. 30, 1992]

§ 405.706 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by HCFA along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* HCFA may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983]

§ 405.708 Effect of initial determination.

(a) The initial determination under § 405.704 (a) or (b) shall be final and binding upon the individual on whose behalf payment under part A has been requested or, if such individual is deceased, upon the representative of such individual's estate, unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such individual (or the representative of such individual's estate if the individual is deceased) shall be the party to such initial determination.

(b) The initial determination under § 405.704(c) shall be final and binding upon the provider of services unless it is reconsidered in accordance with §§ 405.710 through 405.717 or revised in accordance with § 405.750. Such provider of services shall be the party to such initial determination.

[55 FR 11021, Mar. 26, 1990]

§ 405.710 Right to reconsideration.

(a) An individual who is a party to an initial determination, as specified in § 405.704 (a) and (b), (or if such individual is deceased, the representative of such individual's estate) and who is dissatisfied with the initial determination may request a reconsideration of such determination in accordance with § 405.711 regardless of the amount in controversy.

(b) A provider of services who is a party to an initial determination (as specified in § 405.704(c)) and who is dissatisfied with such initial determination may request a reconsideration of such determination in accordance with § 405.711, regardless of the amount in controversy, but only if the individual on whose behalf the request for payment was made has indicated in writing that he does not intend to request reconsideration of the intermediary's initial determination on such request for payment, or if the intermediary has made a finding (see § 405.704(c)) that such individual did not know or could not reasonably have been expected to know that the expenses incurred for the items or services for which such request for payment was made were not reimbursable by reason of § 411.15(g) or § 411.15(k).

[55 FR 11021, Mar. 26, 1990]

§ 405.711 Time and place of filing request for reconsideration.

The request for reconsideration shall be made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368) filed at an office of the Railroad Retirement Board, within 60 days after the date of receipt of notice of initial determination, unless such time is extended as provided in § 405.712. A request for reconsideration which is filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the Health Care Financing Administration as of the date it is filed with the intermediary. For purposes of this section, the date of receipt of notice of the initial determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.712 Extension of time to request reconsideration.

If a party to an initial determination desires to file a request for reconsideration after the time for filing such request in accordance with § 405.711 has passed, such party may file a petition with the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board, for an extension of time for the filing of such request. Such petition shall be in writing and shall state the reasons why the request for reconsideration was not filed within the required time. For good cause shown, the Health Care Financing Administration may extend the time for filing the request for reconsideration.

§ 405.714 Withdrawal of request for reconsideration.

A request for reconsideration may be withdrawn by the party to the initial determination who filed the request or by his representative provided that the withdrawal is made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or, in the case of a qualified railroad retirement beneficiary, with the Railroad Retirement Board prior to the date of the mailing of the notice of reconsidered determination. A withdrawal filed with the intermediary which received the request for payment submitted on behalf of the individual is considered to have been filed with the Health Care Financing Administration as of the date it is filed with the intermediary.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.715 Reconsidered determination.

(a) In reconsidering an initial determination, the Health Care Financing Administration shall review such initial determination, the evidence and findings upon which such determination was based, and any additional evidence submitted to the Social Security Administration or the Health Care Financing Administration or otherwise obtained by the intermediary or the Health Care Financing Administration; and shall make a determination affirming or revising, in whole or in part, such initial determination.

(b) If the request for reconsideration is filed by an individual with respect to an initial determination specified in § 405.704(b)(12), the provider of services who furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto. If pursuant to § 405.710(b) a request for reconsideration is filed by a provider of services with respect to an individual determination under § 405.704(c), the individual who was furnished the items or services shall, prior to the making of the reconsidered determination, be made a party thereto.

[55 FR 11021, Mar. 26, 1990]

§ 405.716 Notice of reconsidered determination.

Written notice of the reconsidered determination shall be mailed by the Health Care Financing Administration to the parties and their representatives at their last known addresses. Such notice shall state the specific reasons for the reconsidered determination and shall advise the parties of their right

to a hearing if the amount in controversy is $100 or more, or, if appropriate, advise them of the requirements for use of the expedited appeals process (see § 405.718).

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.717 Effect of a reconsidered determination.

The reconsidered determination shall be final and binding upon all parties unless a request for a hearing is filed with the Social Security Administration or the Health Care Financing Administration within 60 days after the date of receipt of notice of the reconsidered determination by such parties, or unless the reconsidered determination is revised in accordance with the provisions of § 405.750, or unless the expedited appeals process is used in accordance with § 405.718a. For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718 Expedited appeals process; conditions for use of such process.

In cases in which a reconsideration determination has been made or a higher level of appeal has been reached, an expedited appeals process may be used in lieu of the hearing and Departmental Appeals Board review, if the following conditions are met:

(a) A reconsideration determination has been made by the Secretary; and

(b) The individual is a party referred to in § 405.718b; and

(c) The individual has filed a written request for the expedited appeals process; and

(d) The individual has alleged, and the Secretary agrees, that the only factor precluding a favorable determination with respect to a matter referred to in § 405.704, is a statutory provision which the individual alleges to be unconstitutional; and

(e) Where more than one individual is a party referred to in § 405.718b, each and every party concurs in the request for the expedited appeals process.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 405.718a Expedited appeals process; place and time of filing request.

(a) *Place of filing request.* The request for the expedited appeals process must be made in writing and filed:

(1) At an office of the Social Security Administration or the Health Care Financing Administration; or

(2) In the case of an individual in the Philippines, at the Veterans Administration Regional Office in the Philippines or with a presiding officer; or

(3) In the case of a qualified railroad retirement beneficiary (see 20 CFR 404.368), at an office of the Railroad Retirement Board.

(b) *Time of filing request.* The request for the expedited appeals process must be filed at one of the following times:

(1) No later than 60 days after the date of receipt of notice of the reconsidered determination, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this paragraph, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary; or

(2) If a request for hearing has been timely filed (see § 405.722), at any time prior to the individual's receipt of notice of the presiding officer's decision; or

(3) Within 60 days after the date of receipt of notice of the presiding officer's decision or dismissal, unless the time is extended in accordance with the standards set out in 20 CFR 404.925(c). For purposes of this paragraph, the date of receipt of notice of the presiding officer's decision or dismissal shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary; or

(4) If a request for review by the Departmental Appeals Board has been timely filed (see 20 CFR 404.968) at any time prior to receipt by such individual

of notice of the Departmental Appeals Board's final action.

[40 FR 53387, Nov. 18, 1975, as amended at 41 FR 47917, Nov. 1, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73933, Nov. 7, 1980; 61 FR 32348, June 24, 1996]

§ 405.718b Expedited appeals process; parties.

The parties to the expedited appeals process shall be the person or persons who were parties to the reconsideration determination in question and, if appropriate, parties to the hearing.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718c Expedited appeals process; agreement requirements.

(a)(1) An authorized representative of the Secretary shall, if he determines that all conditions for the use of the expedited appeals process are met (see § 405.718), prepare an agreement for signature of the party (parties) and an authorized representative of the Secretary.

(2)(i) Where a request for hearing has been filed, but prior to issuance of a decision a request for the expedited appeals process is filed, the Chief Administrative Law Judge of the Bureau of Hearings and Appeals, or his designee, shall determine if the conditions required for entering an agreement are met.

(ii) Where a hearing decision was the last action, or where a request for review is pending before the Departmental Appeals Board, and a request for the expedited appeals process is filed, the Chairman or Deputy Chairman of the Departmental Appeals Board or the Chairman's designee, shall determine if the conditions required for an agreement are met.

(b) An agreement with respect to the expedited appeals process shall provide that:

(1) The facts involved in the claim are not in dispute; and

(2) Except as indicated in paragraph (b)(3) of this section, the Secretary's interpretation of the law is not in dispute; and

(3) The sole issue(s) in dispute is the application of a statutory provision(s) which is described therein and which is alleged to be unconstitutional by the party requesting use of such process; and

(4) Except for the provision challenged, the right(s) of the party is established; and

(5) The determination or decision made by the Secretary is final for purposes of section 205(g) of the Act.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 405.718d Expedited appeals process; effect of agreement.

The agreement described in § 405.718c, when signed, shall constitute a waiver by the parties and the Secretary with respect to the need of the parties to pursue the remaining steps of the administrative appeals process, and the period for filing a civil action in a district court of the United States, as provided in section 205(g) of the Social Security Act, shall begin as of the date on which the party (parties) and the authorized representative of the Secretary sign the agreement. Any civil action under the expedited appeals process must be filed within 60 days following the date on which the agreement is signed by, or on behalf of, the Secretary.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.718e Effect of a request that does not result in agreement.

If a request for the expedited appeals process does not meet all the conditions for the use of the process, the Secretary shall so advise the party (parties) and shall treat the request as a request for reconsideration, a hearing, or Departmental Appeals Board review, whichever is appropriate.

[40 FR 53387, Nov. 18, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 32348, June 24, 1996]

§ 405.720 Hearing; right to hearing.

A person has a right to a hearing regarding any initial determination made under § 405.704 if:

(a) Such initial determination has been reconsidered by the Health Care Financing Administration;

(b) Such person was a party to the reconsidered determination;

(c) Such person or his representative has filed a written request for a hearing in accordance with the procedure described in § 405.722; and

(d) The amount in controversy is $100 or more.

[40 FR 1025, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.722 Time and place of filing request for a hearing.

The request for a hearing shall be made in writing and filed at an office of the Social Security Administration or the Health Care Financing Administration or with a presiding officer, or, in the case of a qualified railroad retirement beneficiary, at an office of the Railroad Retirement Board. Such request must be filed within 60 days after the date of receipt of notice of the reconsidered determination by such individual, except where the time is extended as provided in 20 CFR 404.933(c). For purposes of this section, the date of receipt of notice of the reconsidered determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

[45 FR 73933, Nov. 7, 1980]

§ 405.724 Departmental Appeals Board review.

Departmental Appeals Board review is provided by 20 CFR 404.967.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996]

§ 405.730 Court review.

To the extent authorized by section 1869, section 1876(f), and section 1879(d) of the Act, a party to a decision of the Departmental Appeals Board (see 20 CFR 404.979) or the decision of a presiding officer where the request for review by the Departmental Appeals Board was denied, may obtain a court review where the amount in controversy after Departmental Appeals Board review is $1,000 or more, by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act (see 20 CFR 422.210 for the filing procedure). A party to a reconsidered determination may obtain a court review where the amount in controversy is $1,000 or more and he requests and meets the conditions for the expedited appeals process (see § 405.718).

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996]

§ 405.740 Principles for determining the amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a hearing ($100), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more providers to meet the $100 hearing threshold and a single provider may aggregate claims for services provided to one or more beneficiaries to meet the $100 hearing threshold.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s).

(4) When requesting a hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified below, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for a hearing ($100). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the intermediary and less any deductible and coinsurance

amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different provider(s) if the claims involve common issues of law and fact;

(ii) Two or more providers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary; or

(iii) Two or more providers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been reconsidered and a request for hearing has been made within 60 days after receipt of the reconsideration determination(s). Moreover, in the request for hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the administrative law judge (ALJ).

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ also makes the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under § 411.400 of this chapter or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid pursuant to § 411.400 of this chapter or had such liability not been limited pursuant to § 411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amounts in controversy for a hearing.

[59 FR 12181, Mar. 16, 1994]

§ 405.745 Amount in controversy ascertained after reconsideration.

For the purpose of determining whether a party to a reconsidered determination is entitled to a hearing, the amount in controversey after the reconsideration action rather than the amount in controversy initially at issue shall be controlling.

[40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.747 Dismissal of request for hearing; amount in controversy less than $100.

The presiding officer shall, without holding a hearing, dismiss the request for hearing if the request for hearing plainly shows that less than $100 is in controversy. If a hearing is held and the presiding officer finds that the amount in controversy is less than $100, the presiding officer shall dismiss the request for hearing and will not rule on the substantive issues involved in the appeal.

§ 405.750 Time period for reopening initial, revised, or reconsidered determinations and decisions or revised decisions of a presiding officer or the Departmental Appeals Board; finality of determinations and decisions.

(a) *Reopenings concerning applications and entitlement.* A determination, or decision, or revised determination or decision made by the Social Security Administration concerning any matter under § 405.704(a), may be reopened and revised under 20 CFR 404.988 (Conditions for reopening).

(b) *Reopenings concerning a request for payment.* An initial, revised, or reconsidered determination of the Health Care Financing Administration, or a decision or revised decision of a presiding officer or of the Departmental Appeals Board, with respect to an individual's rights concerning a request for payment under Part A of Medicare, which is otherwise final under 20 CFR 404.955 or 404.981 and 405.708, or 405.717 of this subpart may be reopened:

(1) Within 12 months from the date of the notice of the initial or reconsidered determination to the party to such determination;

(2) After such 12-month period, but within 4 years after the date of the notice of the initial determination to the individual, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.988(b) and 404.989); or

(3) At any time, when:

(i) Such initial, revised, or reconsidered determination or such decision or revised decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting clerical error or error on the face of the evidence on which such determination or decision was based; or

(ii) Such initial, revised, or reconsidered determination or such decision or revised decision was procured by fraud or similar fault of the beneficiary or some other person.

[45 FR 73933, Nov. 7, 1980, as amended at 61 FR 32348, June 24, 1996]

§ 405.753 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1842(b)(3)(C), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b)).

SOURCE: 32 FR 18028, Dec. 16, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.801 Title XVIII, Part B—General.

(a) Section 1842(b)(3)(C) of the Act provides that a carrier shall establish and maintain procedures under which an individual enrolled in the supplementary medical insurance plan (see subpart B of this part) is provided with the opportunity for a hearing by the carrier when the amount in controversy is $100 or more as determined in accordance with § 405.820(b) and he is dissatisfied with the carrier's determination denying a request for payment, or with the amount of payment under the supplementary medical insurance plan or when he believes that the request for payment is not being acted upon with reasonable promptness. A physician or other person who furnishes items or services to a person enrolled under the supplementary medical insurance plan and who accepts an assignment from the enrollee has the same right as the enrollee to appeal the carrier's determination.

(b) As used in this section, the term *with reasonable promptness* shall mean a period of 60 consecutive days after the receipt by the carrier of a request for payment.

(c) Procedures governing determinations as to whether an individual is entitled to supplementary medical insurance, which implement section 1869(a) of the Social Security Act, are covered in subpart G of this part and 20 CFR part 404, subpart J.

[39 FR 12096, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 45 FR 73945, Nov. 7, 1980]

§ 405.802 Definitions.

As used in subpart H of this part, the term—

Appellant designates the beneficiary, assignee or other person or entity that has filed an appeal concerning a particular determination of benefits under Medicare part B. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Assignee means a physician or supplier who furnishes services to a beneficiary under Medicare part B and who has accepted a valid assignment executed by the beneficiary.

Assignment means the transfer by the assignor of his or her claim for payment to the assignee in return for the latter's promise not to charge more for his or her services than the carrier finds to be the reasonable charge or other approved amount.

Assignor means a beneficiary under Medicare part B whose physician or supplier has taken assignment of a claim.

Carrier means an organization which has entered into a contract with the Secretary pursuant to section 1842 of the Act and which is authorized to make determinations with respect to part B of title XVIII of the Act. For purposes of this subpart, the term carrier also refers to an intermediary that has entered into a contract with the Secretary under section 1816 of the Act and is authorized to make determinations with respect to part B provider services, as specified in § 421.5(c) of this chapter.

Common issues of law and fact, with respect to the aggregation of claims by two or more appellants to meet the minimum amount in controversy needed for an ALJ hearing, occurs when the claims sought to be aggregated are denied or reduced for similar reasons and arise from a similar fact pattern material to the reason the claims are denied.

Delivery of similar or related services, with respect to the aggregation of claims by two or more physician/supplier appellants to meet the minimum amount in controversy needed for an ALJ hearing, means like or coordinated services or items provided to the same beneficiary by the appellants.

Representative means an individual meeting the conditions described in §§ 405.870 through 405.871.

[59 FR 12182, Mar. 16, 1994]

§ 405.803 Initial determination.

(a) The carrier (or the hearing officer where a claim is ''not acted upon with reasonable promptness'' (see § 405.801)) shall, on the basis of all of the evidence, make an initial determination with respect to an applicant's claim for benefits under Part B of title XVIII.

(b) An initial determination for purposes of this subpart includes among others, a determination as to whether items and services furnished are covered; whether the deductible has been met; whether the receipted bill or other evidence of payment is acceptable; whether the charges for items or services furnished are reasonable; and if the items or services furnished an enrollee by a physician or a supplier of services pursuant to an assignment under § 424.55 of this chapter are not covered by reason of § 405.310(k), whether such enrollee, physician, or supplier knew or could reasonably have been expected to know that such items or services were excluded from coverage.

(c) Carriers (or hearing officers where a claim is not acted upon with reasonable promptness (see § 405.801)) do not make determinations with respect to the following, which are not initial determinations for purposes of this subpart:

(1) Any issue or factor for which the Social Security Administration or the Health Care Financing Administration has sole responsibility (for example, whether an independent laboratory meets the conditions for coverage of services; whether a Medicare overpayment claim should be compromised, or collection action terminated or suspended); or

(2) Any issue or factor which relates to hospital insurance benefits under Part A of title XVIII of the Act.

[39 FR 12097, Apr. 3, 1974, as amended at 40 FR 1026, Jan. 6, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 59382, Dec. 20, 1978; 45 FR 73945, Nov. 7, 1980; 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988]

§ 405.804 Notice of initial determination.

After a carrier has made an initial determination on a request for payment written notice of this determination shall be mailed to each party to the determination at his last known address. The notice of the determination shall inform each party to the determination of his right to have such determination reviewed.

§ 405.805 Parties to the initial determination.

The parties to the initial determination (see § 405.803) may be any party described in § 405.802(b).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.806 Effect of initial determination.

The initial determination shall be final and binding upon the party or parties to such determination unless it is reviewed in accordance with §§ 405.810 through 405.812, or is revised in accordance with § 405.841 by the carrier (or by the hearing officer presiding where a claim is not acted upon with reasonable promptness (see § 405.801)).

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.807 Review of initial determination.

(a) *General.* A party to an initial determination by a carrier, who is dissatisfied with such initial determination, may request that the carrier review such determination. If a review is requested, such action shall not constitute a waiver of the right to hearing (see § 405.820) subsequent to such review.

(b) *Place of filing request.* A request for a carrier to review the initial determination is to be made in writing and filed at an office of the carrier or at an office of the Social Security Administration or the Health Care Financing Administration.

(c) *Time of filing request.* The carrier shall provide a period of 6 months after the date of the notice of its initial determination within which a party to the initial determination may request review. The carrier may, upon request by the party affected, extend the period for requesting the review.

(d) *Request for review.* Any clear expression in writing by a party to an initial determination which indicates, in effect, that he is dissatisfied with such determination by the carrier and wants to appeal the matter further constitutes a request for review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.808 Parties to the review.

The parties to the review (as provided for in § 405.807(a)) shall be the persons who were parties to the carrier's initial determination as described in § 405.805, and any other party whose rights with respect to the particular claim being reviewed may be affected by such review.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.809 Opportunity to submit evidence.

The parties to the review (as provided for in § 405.807(a)) shall have a reasonable opportunity to submit written evidence and contentions as to fact or law relative to the claim at issue.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.810 Review determination.

Subject to the provisions of §§ 405.807 through 405.809, the carrier shall review the claim in dispute and, upon the basis of the evidence of record, shall make a separate determination affirming or revising in whole or in part the findings and determination in question.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.811 Notice of review determination.

Written notice of the review determination is mailed to a party at his or her last known address. The review determination states the basis of the determination and advises the party of his or her right to a carrier hearing when the amount in controversy is $100 or more as determined in accordance with § 405.817. The notice states the place and manner of requesting a carrier hearing as well as the time limit

under which a hearing must be requested (see § 405.821).

[59 FR 12182, Mar. 16, 1994]

§ 405.812 Effect of review determination.

The review determination is final and binding upon all parties to the review unless a carrier hearing decision is issued pursuant to a request for hearing made in accordance with § 405.821 or is revised as a result of reopening in accordance with § 405.841.

[59 FR 12182, Mar. 16, 1994]

§ 405.815 Amount in controversy for carrier hearing, ALJ hearing and judicial review.

Any party designated in § 405.822 is entitled to a carrier hearing after a review determination has been made by the carrier if the amount remaining in controversy is $100 or more and the party meets the requirements of § 405.821 of this subpart. To be entitled to a hearing before an ALJ following the carrier hearing, the amount remaining in controversy must be $500 or more, and for judicial review following the ALJ hearing and Departmental Appeals Board Review, the amount remaining in controversy must be $1000 or more.

[59 FR 12182, Mar. 16, 1994, as amended at 61 FR 32348, June 24, 1996]

§ 405.817 Principles for determining amount in controversy.

(a) *Individual appellants.* For the purpose of determining whether an individual appellant meets the minimum amount in controversy needed for a carrier hearing ($100) or ALJ hearing ($500), the following rules apply:

(1) The amount in controversy is computed as the actual amount charged the individual for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) A single beneficiary may aggregate claims from two or more physicians/suppliers to meet the $100 or $500 thresholds. A single physician/supplier may aggregate claims from two or more beneficiaries to meet the $100 or $500 threshold levels of appeal.

(3) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for a carrier hearing only if the claims have previously been reviewed and a request for hearing has been made within six months after the date of the review determination(s).

(4) In either of the circumstances specified in paragraph (a)(2) of this section, two or more claims may be aggregated by an individual appellant to meet the amount in controversy for an ALJ hearing only if the claims have previously been decided by a carrier hearing officer and a request for an ALJ hearing has been made within 60 days after receipt of the carrier hearing officer decision(s).

(5) When requesting a carrier hearing or an ALJ hearing, the appellant must specify in his or her appeal request the specific claims to be aggregated.

(b) *Two or more appellants.* As specified in this paragraph, under section 1869(b)(2) of the Act, two or more appellants may aggregate their claims together to meet the minimum amount in controversy needed for an ALJ hearing ($500). The right to aggregate under this statutory provision applies to claims for items and services furnished on or after January 1, 1987.

(1) The aggregate amount in controversy is computed as the actual amount charged the individual(s) for the items and services in question, less any amount for which payment has been made by the carrier and less any deductible and coinsurance amounts applicable in the particular case.

(2) In determining the amount in controversy, two or more appellants may aggregate their claims together under the following circumstances:

(i) Two or more beneficiaries may combine claims representing services from the same or different physician(s) or supplier(s) if the claims involve common issues of law and fact;

(ii) Two or more physicians/suppliers may combine their claims if the claims involve the delivery of similar or related services to the same beneficiary;

(iii) Two or more physicians/suppliers may combine their claims if the claims involve common issues of law and fact with respect to services furnished to two or more beneficiaries.

(iv) In any of the circumstances specified in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, the claims may be aggregated only if the claims have previously been decided by a carrier hearing officer(s) and a request for ALJ hearing has been made within 60 days after receipt of the carrier hearing officer decision(s). Moreover, in a request for ALJ hearing, the appellants must specify the claims that they seek to aggregate.

(c) The determination as to whether the amount in controversy is $100 or more is made by the carrier hearing officer. The determination as to whether the amount in controversy is $500 or more is made by the ALJ.

(d) In determining the amount in controversy under paragraph (b) of this section, the ALJ will also make the determination as to what constitutes ''similar or related services'' or ''common issues of law and fact.''

(e) When a civil action is filed by either an individual appellant or two or more appellants, the Secretary may assert that the aggregation principles contained in this subpart may be applied to determine the amount in controversy for judicial review ($1000).

(f) Notwithstanding the provisions of paragraphs (a)(1) and (b)(1) of this section, when payment is made for certain excluded services under §411.400 of this chapter or the liability of the beneficiary for those services is limited under §411.402 of this chapter, the amount in controversy is computed as the amount that would have been charged the beneficiary for the items or services in question, less any deductible and coinsurance amounts applicable in the particular case, had such expenses not been paid under §411.400 of this chapter or had such liability not been limited under §411.402 of this chapter.

(g) Under this subpart, an appellant may not combine part A and part B claims together to meet the requisite amount in controversy for a carrier hearing or ALJ hearing. HMO, CMP and HCPP appellants under part 417 of this chapter may combine part A and part B claims together to meet the requisite amount in controversy for a hearing.

[59 FR 12182, Mar. 16, 1994]

§ 405.821 Request for carrier hearing.

(a) A request for a carrier hearing is any clear expression in writing by a claimant asking for a hearing to adjudicate a claim when not acted upon with reasonable promptness or by a party to a review determination who states, in effect, that he or she is dissatisfied with the carrier's review determination and wants further opportunity to appeal the matter to the carrier.

(b) The hearing request must be filed at an office of the carrier or at an office of SSA or HCFA.

(c) Except when a carrier hearing is held because the carrier did not act upon a claim with reasonable promptness (see §405.801), a party to the review determination may request a carrier hearing within six months after the date of the notice of the review determination. The carrier may, upon request by the party affected, extend the period for filing the request for hearing.

[59 FR 12183, Mar. 16, 1994]

§ 405.822 Parties to a carrier hearing.

The parties to a hearing shall be the persons who were parties to the carrier's review determination (§405.808) which is in question. Any other person may be made a party if that person's rights with respect to supplementary medical insurance benefits may be prejudiced by the decision.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.823 Carrier hearing officer.

Any hearing provided for in this subpart shall be conducted by a hearing officer designated by the appropriate official of the carrier.

[39 FR 12097, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.824 Disqualification of carrier hearing officer.

A hearing officer shall not conduct a hearing in any case in which he is prejudiced or partial with respect to any party, or if he has any interest in the matter before him. Notice of any objection with respect to the hearing officer who will conduct the hearing shall be made by the objecting party at his earliest opportunity. The hearing officer shall consider such objection and shall, at his discretion, withdraw. If the hearing officer withdraws, the appropriate official of the carrier shall designate another hearing officer to conduct the hearing. If the hearing officer does not withdraw, the objecting party may present his objections to the carrier for consideration at any time prior to the issuance of a decision. The carrier shall review the request and take appropriate action. The fact that a hearing officer is an employee of the carrier may not serve as prima facie cause for disqualification.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.825 Location of carrier hearing.

(a) *Time and place.* The hearing officer shall fix a time and place for the hearing reasonably convenient to the requesting party and not inconsistent with the public interest.

(b) *Adjournment or postponement.* The hearing officer may, for a good and sufficient reason, fix a new time and/or place for the hearing; he may change the time and place for the hearing or adjourn the hearing on his own motion upon reasonable notification to the parties.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.826 Notice of carrier hearing.

The notice of hearing is to include notice of the time and place of the hearing; information as to the specific issues to be determined; and the matters on which findings will be made and conclusions will be reached. The notice is to contain sufficient information about the hearing procedure (including the party's right to representation) for effective preparation for the hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.830 Conduct of the carrier hearing.

(a) *General.* Hearings shall be open to the parties and to such other persons as the hearing officer deems necessary and proper for the orderly and efficient conduct of the hearing. The hearing officer shall inquire fully into the matters at issue and shall receive in evidence the testimony of witnesses and any documents which are relevant and material to such matters. The parties shall be provided an opportunity to enter any objection to the inclusion of any document. The order in which evidence and allegations shall be presented and the procedure at the hearing, except as this subpart otherwise expressly provides, shall be at the discretion of the hearing officer and of such nature as to afford the parties a proper hearing.

(b) *Evidence.* Evidence may be received at the hearing even though inadmissible under rules of evidence applicable to court procedures.

(c) *Witnesses.* The hearing officer may examine the witnesses and shall allow the parties or their representatives to do so. If the hearing officer conducts the examination of a witness, he may allow the parties to suggest matters upon which they desire the witness to be questioned, and the hearing officer shall question the witness with respect to such matters if they are relevant and material to any issue pending for decision before him.

(d) *Oral argument and written allegations.* The parties, upon their request shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements or allegations of facts or law.

(e) *Consolidated issues.* When one or more new issues are raised at any time after a request for hearing has been made, but before the mailing of notice of the decision, the hearing officer

may, at his discretion, consider the issues along with the other issues pending before him on the same request for hearing.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.831 Waiver of right to appear and present evidence.

If all parties waive their right to appear before the hearing officer and present evidence and contentions personally or by representative, it shall not be necessary for the hearing officer to give notice of or conduct a formal hearing as provided in §§ 405.825 through 405.830. A waiver of the right to appear is to be in writing and filed with the hearing officer or the carrier. Such waiver may be withdrawn by a party at any time prior to the mailing of notice of the decision in the case. Even though all of the parties have filed a waiver of the right to appear and present evidence and contentions at a hearing before the hearing officer, the hearing officer may, nevertheless, give notice of a time and place and conduct a hearing as provided in §§ 405.825 through 405.830, if he believes that the personal appearance and testimony of the party or parties would assist him to ascertain the facts at issue in the case. For purposes of this section, failure of the parties to appear shall not be cause for a finding of abandonment and the hearing officer shall make his decision on the basis of all evidence adduced.

§ 405.832 Dismissal of request for carrier hearing.

(a) *By application of party*. With the approval of the hearing officer, a request for a hearing may be withdrawn or dismissed at any time prior to the mailing of notice of the decision upon the application of the party or parties filing the request for such hearing. A party may request a dismissal by filing a written notice of such request with the carrier, the hearing officer or orally stating such request at the hearing. The dismissal of a request for hearing shall be final and binding unless vacated (see paragraph (d) of this section).

(b) *Dismissal by abandonment of party*. A hearing officer may dismiss a request for hearing upon abandonment by the party or parties who filed the request. A party shall be deemed to have abandoned a request for hearing, other than where personal appearance is waived in accordance with § 405.831, if neither the party nor his representative appears at the time and place fixed for the hearing and within 10 days after the mailing of a notice to him by the hearing officer to show cause, such party does not show good and sufficient cause for such failure to appear and failure to notify the hearing officer prior to the time fixed for hearing that he cannot appear.

(c) *Dismissal for cause.* The hearing officer may, on his own motion, dismiss a hearing request, either entirely or as to any stated issue, under either of the following circumstances:

(1) Where the party requesting a hearing is not a proper party under § 405.822 or does not otherwise have a right to a hearing under section 1842(b)(3)(c) of the Act; or

(2) Where the party who filed the hearing request dies and there is no information before the hearing officer showing that an individual who is not a party may be prejudiced by the carrier's determination.

(d) *Dismissal without prejudice.* The hearing officer may on his own motion dismiss without prejudice a hearing request where the amount in controversy is less than $100.

(e) *Vacation of dismissal.* A hearing officer may, on request of a party and for good and sufficient cause shown, vacate any dismissal of a request for hearing at any time within 6 months from the date of mailing notice of the dismissal to the party requesting the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.833 Record of carrier hearing.

A complete record of the proceedings at the hearing shall be made. The testimony shall be transcribed and copies of other documentary evidence shall be reproduced in any case when directed by the hearing officer, the carrier or

the Health Care Financing Administration. The record will also be transcribed and reproduced at the request of a party to the hearing provided he bears the cost thereof.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.834 Carrier hearing officer's decision.

As soon as practicable after the close of a hearing, the hearing officer, except as provided in this subpart, shall make a decision in the case which shall be based upon the evidence adduced at the hearing (see §§ 405.820 to 405.830) or otherwise included in the hearing record (see § 405.833). The decision shall be made in writing and contain findings of fact and statement of reasons. A copy of the decision shall be mailed to each party to the hearing at his last known address.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.835 Effect of carrier hearing officer's decision.

The hearing officer's decision, provided for in § 405.834, shall be final and binding upon all parties to the hearing unless it is revised in accordance with § 405.841.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.841 Reopening initial or review determination of the carrier, and decision of a carrier hearing officer.

An initial or review determination of a carrier or a decision of a hearing officer may be reopened by such carrier or hearing officer:

(a) Within 12 months from the date of the notice of such initial or review determination or decision to the party to such determination or decision; or

(b) After such 12-month period, but within 4 years from the date of the notice of the initial determination to the party to such determination, upon establishment of good cause for reopening such determination or decision (see 20 CFR 404.958); or

(c) At any time, when:

(1) Such initial or review determination or decision was procured by fraud or similar fault of the beneficiary or some other person, or

(2) Such initial or review determination or decision is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error or error on the face of the evidence on which such determination or decision was based.

[39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.842 Notice of reopening and revision.

(a) *Notice.* When any determination or decision is reopened as provided in § 405.841, notice of such reopening shall be mailed to the parties to such determination or decision at their last known addresses. A notice of revision following a reopening of a decision, shall be mailed to the parties and shall state the basis for the revised determination or decision.

(b) *Effect of revised determination.* The revision of a determination (see § 405.841) shall be final and binding upon all parties thereto unless a party files a written request for a hearing with respect to a revised determination when the amount in controversy is $100 or more.

[32 FR 18028, Dec. 16, 1967, as amended at 39 FR 12098, Apr. 3, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.850 Change of ruling or legal precedent.

Change of a legal interpretation or administrative ruling upon which a determination or decision was made shall not be considered as good and sufficient reason for reopening the determination or decision.

§ 405.860 Authority of the carrier hearing officer.

The hearing officer in exercising the authority to conduct a hearing under section 1842(b)(3)(C) of the Act is to comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with policy statements, instructions and other guides issued by the Health Care Financing Administration in accordance

with the Secretary's agreement with the carriers.

[32 FR 18028, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 59 FR 12183, Mar. 16, 1994]

§ 405.870 Appointment of representative.

A party to an initial determination, informal review or hearing as provided in §§ 405.803 through 405.934, may appoint as his representative in any such proceeding any person qualified under § 405.871. Where the representative is an attorney, in the absence of information to the contrary, his representation that he has such authority shall be accepted as evidence of the attorney's authority to represent a party.

§ 405.871 Qualifications of representatives.

Any individual may be appointed to act as representative in accordance with § 405.870, unless he is disqualified or suspended from acting as a representative in proceedings before the Social Security Administration or the Health Care Financing Administration or unless otherwise prohibited by law.

§ 405.872 Authority of representatives.

A representative, appointed and qualified as provided in §§ 405.870 and 405.871, may make or give, on behalf of the party he represents, any request or notice relative to any proceeding before the carrier including review and hearing. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to the claim of such party to the same extent as such party. Notice to any party or any action, determination, or decision, or request to any party for the production of evidence, shall be sent to the representative of such party.

§ 405.874 Appeals of carrier decisions that supplier standards are not met.

(a) An entity serving as a National Supplier Clearinghouse must act promptly to determine if any entity submitting a request for a billing number as a Medicare supplier of part B items meets the standards set forth in part 424. Effective July 1, 1993, the National Supplier Clearinghouse must accept, reject or request additional information within 15 days of the receipt of an enrollment application.

(b) If the National Supplier Clearinghouse disallows an entity's request for a billing number or revokes, with the concurrence of HCFA, an entity's billing number, the National Supplier Clearinghouse notifies the entity by certified mail. Revocation is effective 15 days after the National Supplier Clearinghouse mails notice of its determination. The carrier disallows payment for items furnished by the supplier beginning with that effective date. The notice must inform the entity of the reason for the rejection or revocation, its right to appeal, the date by which it must file that appeal (90 days after the postmark of the notice) and the address to which the appeal must be sent in writing.

(c) A fair hearing officer not involved in the original determination to disallow an entity's request for a billing number, or to revoke an entity's billing number, must schedule a hearing to be held within one week of receipt of an appeal, or later at the request of the entity. Both the entity and carrier may offer evidence. The hearing officer issues notice of his/her decision within 2 weeks of the hearing. The notice is sent by certified letter to HCFA, the carrier, and the appealing entity. This notice must include information about the supplier's further right to appeal, the carrier's right to appeal, the date by which the appeal must be filed (90 days after the postmark of the notice) and the address to which the appeals must be sent in writing. Either the carrier or entity may appeal the hearings officer's decision to HCFA.

(d) A HCFA official, designated by the Administrator of HCFA, must make an appeal decision based on the evidence presented to the fair hearing officer and his or her decision. The HCFA official requests any additional information he or she deems necessary from either the carrier or the entity within two weeks of receipt by the HCFA of the appeal. Notice of the HCFA official's decision—

(1) Is issued within two weeks of when the last information is received is

received by the HCFA official, or four weeks of when the information is requested, whichever is shorter, unless the party appealing the fair hearing decision requests a delay;

(2) Is sent by the HCFA official by certified mail to both the carrier and the entity; and

(3) Contains information on any further appeals the entity and carrier may have.

(e) A billing number is not issued, or remains revoked, and payment is not made, for items or services furnished by any entity which a carrier determines does not qualify for a billing number, until the carrier (upon reapplication of the entity), a fair hearing officer, or a HCFA official designated to hear such appeals, determines that the entity qualifies for a billing number. Any claims for items or services furnished after revocation of the supplier's billing number and submitted by the entity during the appeals period are held and not processed, i.e., are neither approved, denied or developed, until all administrative appeals have been exhausted. If an entity is determined not to have qualified for a billing number in one period but to have qualified in another, the carrier pays for claims for items sold or rented to beneficiaries during the period the entity qualified as a supplier. If there is evidence of an overpayment, see subpart C of part 405 of this Chapter.

(f) A billing number may be reinstated after revocation when an entity completes a corrective action plan, to which HCFA has agreed, and provided sufficient assurance of its intent to comply fully with the supplier standards.

[57 FR 27305, June 18, 1992]

§405.877 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under §405.203 may not be reviewed by an administrative law judge.

[60 FR 48424, Sept. 19, 1995]

Subparts I–Q—[Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of HCFA.

Administrator's review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and §405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and §405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and §405.1835.

Date of filing and *date of submission of materials* mean the day of the mailing (as evidenced by the postmark) or hand-delivery of materials, unless otherwise defined in this subpart.

Date of receipt means the date on the return receipt of ''return receipt requested'' mail, unless otherwise defined in this subpart.

Intermediary determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§413.20 and 413.24(f) of this chapter, the term means a determination of the amount of total reimbursement due the

provider, pursuant to §405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a determination of the total amount of payment due the hospital, pursuant to §405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination'' and ''final determination of the Secretary'', as those phrases are used in section 1878(a) of the Act.

(4) For purposes of §405.374 concerning claims collection activities, the term does not include an action by HCFA with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Intermediary hearing means that hearing provided for in §405.1809.

(b) *General rule*—(1) *Providers.* The principles of reimbursement for determining reasonable cost and prospective payment are contained in parts 413 and 412, respectively, of this chapter. In order to be reimbursed for covered services furnished to Medicare beneficiaries, providers of services are obliged to file cost reports with their intermediaries as specified in §413.24(f) of this chapter. Where the term ''provider'' appears in this subpart, it includes hospitals paid under the prospective payment system for purposes of applying the appeal procedures described in this subpart to those hospitals.

(2) *Other entities participating in Medicare Part A.* In addition to providers of services whose status as such is indicated in the Act, there are entities (such as health maintenance organizations) that do not meet the statutory test for providers of services, which may also participate in Medicare. These entities are required to file periodic cost reports and are reimbursed on the basis of information furnished in the reports. Although the entities do not qualify for Board review, the rules as set forth in this subpart with respect to intermediary hearings are applicable to the entities to the maximum extent possible, for cost-reporting periods ending on or after December 31, 1971, where the amount of program reimbursement in controversy is at least $1,000.

(c) *Effective dates.* (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in §405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31, 1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see part 412 of this chapter), the appeals procedures in §§405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986]

§ 405.1803 Intermediary determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the intermediary must within a reasonable period of time (see §405.1835(b)), furnish the provider and other parties as appropriate (see §405.1805) a written notice reflecting the intermediary's determination of the total amount of reimbursement due the provider. The intermediary must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the intermediary's determination of total program reimbursement due the provider on the basis of

reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the intermediary must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(b) *Requirements for intermediary notices.* The intermediary must include in each notice appropriate references to law, regulations, HCFA Rulings, or program instructions to explain why the intermediary's determination of the amount of program reimbursement for the period differs from the amount the provider claimed. The notice must also inform the provider of its right to an intermediary or Board hearing (see §§405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of the notice.

(c) *Use of notice as basis for recovery of overpayments.* The intermediary's determination as contained in its notice constitutes the basis for making the retroactive adjustment (required by §413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including the suspending of further payments to the provider in order to recover, or to aid in the recovery of, any overpayment identified in the determination to have been made to the provider, notwithstanding any request for hearing on the determination the provider may make under §405.1811 or §405.1835. Any suspension will remain in effect as specified in §405.373(a).

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan 3, 1984; 51 FR 34793, Sept. 30, 1986]

§405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of any budget neutrality adjustment in the prospective payment rates.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984]

§405.1805 Parties to intermediary determination.

The parties to the intermediary's determination are the provider and any other entity found by the intermediary to be a related organization of the provider under §413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§405.1807 Effect of intermediary determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) An intermediary hearing is requested in accordance with §405.1811 and an intermediary hearing decision rendered in accordance with §405.1831; or

(b) The intermediary determination is revised in accordance with §405.1885; or

(c) A Board hearing is requested in accordance with §405.1835 and a hearing decision rendered pursuant thereto.

§ 405.1809 Intermediary hearing procedures.

(a) *Hearings.* Each intermediary must establish and maintain written procedures for intermediary hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the intermediary and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in § 405.1804) under the Medicare program. The procedures must provide for a hearing on the intermediary determination contained in the notice of program reimbursement (§ 405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy.* In order for an intermediary to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§ 405.1811 Right to intermediary hearing; time, place, form, and content of request for intermediary hearing.

(a) A provider that has been furnished a notice of amount of program reimbursement may request an intermediary hearing if it is dissatisfied with the intermediary's determination contained in the notice and the amount in controversy requirement described in § 405.1809 is met. The request must be in writing and be filed with the intermediary within 180 calendar days after the date of the notice. (See § 405.1835(c)). No other individual, entity, or party has the right to an intermediary hearing.

(b) The request must (1) identify the aspect(s) of the determination with which the provider is dissatisfied, and (2) explain why the provider believes the determination on these matters is incorrect, and (3) be submitted with any documentary evidence the provider considers necessary to support its position.

(c) Following the timely filing of the request for hearing, the provider may identify in writing, prior to the onset of the hearing proceedings, additional aspects of the determination with which it is dissatisfied and furnish any documentary evidence in support thereof. If such additional aspects are submitted, the hearing officer may postpone the hearing to allow for his examination of such additional aspects.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 39835, Sept. 1, 1983]

§ 405.1813 Failure to timely request an intermediary hearing.

If a provider requests an intermediary hearing on an intermediary's determination after the time limit prescribed in § 405.1811, the designated intermediary hearing officer or panel of hearing officers will dismiss the request and furnish the provider a written notice that explains the time limitation, except that for good cause shown, the time limit prescribed in § 405.1811 may be extended. However, an extension may not be granted if the extension request is filed more than 3 years after the date of the original notice of the intermediary determination.

[48 FR 39835, Sept. 1, 1983]

§ 405.1815 Parties to the intermediary hearing.

The parties to the intermediary hearing shall be the parties to the intermediary determination and any other entity determined by the intermediary to be a related organization of such provider. Said parties shall be given reasonable notice of the time, date, and place of such hearing. Neither the intermediary nor the Health Care Financing Administration are parties (see § 405.1819).

§ 405.1817 Hearing officer or panel of hearing officers authorized to conduct intermediary hearing; disqualification of officers.

The intermediary hearing provided for in § 405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the intermediary.

Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the intermediary, who shall rule promptly on the objection.

§405.1819 Conduct of intermediary hearing.

The hearing shall be open to all parties thereto (see §405.1815) and to representatives of the intermediary and of the Health Care Financing Administration (see §405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing, he (they) may, at any time prior to the mailing of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

§405.1821 Prehearing discovery and other proceedings prior to the intermediary hearing.

(a) Prehearing discovery shall be permitted upon timely request of any party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the hearing officer(s).

(b) If, in the discretion of the hearing officer(s), the purpose of defining the issues more clearly would be served, the hearing officer(s) may schedule a prehearing conference. For this purpose, a single member of a panel of hearing officers, when such is the case, may be appointed to act for the panel with respect to prehearing activities.

§405.1823 Evidence at intermediary hearing.

Evidence may be received at the intermediary hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§405.1825 Witnesses at intermediary hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§405.1827 Record of intermediary hearing.

A complete recordation of the proceedings at the intermediary hearing shall be made and transcribed in all cases. It shall be made available to any party upon request. The record will not be closed until a decision (see §405.1831) has been issued.

§405.1829 Authority of hearing officer(s) at intermediary hearing.

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (see 42 CFR 401.108),

and with the general instructions issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the intermediary.

(b) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expense incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), shall not be reviewed by the hearing officer(s). Such determination shall be reviewed only in accordance with the applicable provisions of subparts G and H of this part.

§ 405.1831 Intermediary hearing decision and notice.

The hearing officer(s) shall, on a timely basis, render a decision in writing based on the evidence in the record; such decision shall constitute the final determination of the intermediary. In such decision, he will cite applicable law, regulations, HCFA Rulings, and general instructions of the Health Care Financing Administration, as well as findings on all the matters in issue at the hearing. A copy of the decision will be mailed to all parties to the hearing at their last known addresses.

§ 405.1833 Effect of intermediary hearing decision.

The intermediary hearing decision provided for in § 405.1831 shall be final and binding upon all parties to the hearing unless such intermediary determination is revised in accordance with § 405.1885.

§ 405.1835 Right to Board hearing.

(a) *Criteria.* The provider (but no other individual, entity, or party) has a right to a hearing before the Board about any matter designated in § 405.1801(a)(1), if:

(1) An intermediary determination has been made with respect to the provider; and

(2) The provider has filed a written request for a hearing before the Board under the provisions described in § 405.1841(a)(1); and

(3) The amount in controversy (as determined in § 405.1839(a)) is $10,000 or more.

(b) *Prospective payment exceptions.* Except with respect to matters for which administrative or judicial review is not permitted as specified in § 405.1804, hospitals that are paid under the prospective payment system are entitled to hearings before the Board under this section if they otherwise meet the criteria described in paragraph (a) of this section.

(c) *Right to hearing based on late intermediary determination about reasonable cost.* Notwithstanding the provisions of paragraph (a)(1) of this section, the provider also has a right to a hearing before the Board if an intermediary's determination concerning the amount of reasonable cost reimbursement due a provider is not rendered within 12 months after receipt by the intermediary of a provider's perfected cost report or amended cost report (as permitted or as required to furnish sufficient data for purposes of making such determination—see § 405.1803(a)) provided such delay was not occasioned by the fault of the provider.

[48 FR 39835, Sept. 1, 1983]

§ 405.1837 Group appeal.

(a) *Criteria for group appeals.* Subject to paragraph (b) of this section, a group of providers may bring an appeal before the Board but only if—

(1) Each provider in the group is identified as one which would, upon the filing of a request for a hearing before the Board, but without regard to the $10,000 amount in controversy requirement, be entitled to a hearing under § 405.1835;

(2) The matters at issue involve a common question of fact or of interpretation of law, regulations or HCFA Rulings; and

(3) The amount in controversy is, in the aggregate, $50,000 or more.

(b) *Providers under common ownership or control.* Effective April 20, 1983, any appeal filed by providers that are under common ownership or control must be brought by the providers as a group appeal in accordance with the provisions of paragraph (a) of this section with respect to any matters involving an issue common to the providers and for which

the amount in controversy is, in the aggregate, $50,000 or more (see §405.1841(a)(2)). A single provider involved in a group appeal that also wishes to appeal issues that are not common to the other providers in the group must file a separate hearing request (see §405.1841(a)(1)) and must separately meet the requirements in §405.1811 or §405.1835, as applicable.

[48 FR 39836, Sept. 1, 1983]

§405.1839 Amount in controversy.

(a) *Single appeals.* The $1,000 amount in controversy required under §405.1809 for an intermediary hearing and the $10,000 amount in controversy required under §405.1835 for a Board hearing is, as applicable to the matters for which the provider has requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the provider on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable after a recomputation that takes into account any exclusion, exception, adjustment, or additional payment denied the provider under part 412 of this chapter, as applicable;

(ii) The total of the payment due the provider on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed by the provider; and

(iii) The adjusted total reimbursable costs due the provider on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed by the provider.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the provider on a reasonable cost basis from the total reimbursable costs claimed by the provider.

(b) *Group appeals.* The $50,000 amount in controversy required under §405.1837 for group appeals to the Board is, as applicable to the common matters for which the group of providers have requested a hearing, the combined total of the amounts computed as follows:

(1) *Providers under prospective payment.* For providers that are paid under the prospective payment system, by deducting—

(i) The total of the payment due the providers (in the aggregate) on other than a reasonable cost basis under the prospective payment system from the total amount that would be payable to the providers (in the aggregate) after a recomputation that takes into account any applicable exception, exclusion, adjustment, or additional payment denied the providers under part 412 of this chapter.

(ii) The total of the payment due the providers (in the aggregate) on a reasonable cost basis under the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers; and

(iii) The adjusted total reimbursable costs due the providers (in the aggregate) on a reasonable cost basis under other than the prospective payment system from the total reimbursable costs claimed in the aggregate by the providers.

(2) *Providers not under prospective payment.* For providers that are not paid under the prospective payment system, by deducting the adjusted total reimbursable program costs due the providers (in the aggregate) on a reasonable cost basis from the total reimbursable costs claimed in the aggregate by the providers.

[49 FR 323, Jan. 3, 1984]

§405.1841 Time, place, form, and content of request for Board hearing.

(a) *General requirements.* (1) The request for a Board hearing must be filed in writing with the Board within 180 days of the date the notice of the intermediary's determination was mailed to the provider or, where notice of the determination was not timely rendered, within 180 days after the expiration of the period specified in §405.1835(c). Such request for Board hearing must identify the aspects of the determination with which the provider is dissatisfied, explain why the provider believes the determination is incorrect in such particulars, and be

accompanied by any documenting evidence the provider considers necessary to support its position. Prior to the commencement of the hearing proceedings, the provider may identify in writing additional aspects of the intermediary's determination with which it is dissatisfied and furnish any documentary evidence in support thereof.

(2) Effective April 20, 1983, any request for a Board hearing by providers that are under common ownership or control (see § 413.17 of this chapter) must be brought by the providers as a group appeal (see § 405.1837(b)) with respect to any matters at issue involving a question of fact or of interpretation of law, regulations, or HCFA Rulings common to the providers and for which the amount in controversy is $50,000 or more in the aggregate. If a group appeal is filed, the provider seeking the appeal must be separately identified in the request for hearing, which must be prepared and filed consistently with the requirements of paragraph (a)(1) of this section.

(b) *Extension of time limit for good cause.* A request for a Board hearing filed after the time limit prescribed in paragraph (a) of this section shall be dismissed by the Board, except that for good cause shown, the time limit may be extended. However, no such extension shall be granted by the Board if such request is filed more than 3 years after the date the notice of the intermediary's determination is mailed to the provider.

[48 FR 39836, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1842 Expediting Board proceedings.

(a) *Basis and purpose.* This section implements section 1878(f)(1) of the Social Security Act, as amended by section 955 of Public Law 96–499 (42 U.S.C. 1395oo(f)(1)). The amendment provides an opportunity for providers to obtain expedited administrative review when the Board determines that it does not have the authority to decide a question of law, regulation, or HCFA Ruling relevant to the case (see § 405.1867).

(b) *Basic rule.* (1) Except as provided in paragraph (b)(4) of this section, a provider may submit a written request to the Board, with supporting documentation, to determine whether the Board has the authority to decide a question of law, regulations, or HCFA Rulings relevant to and controlling upon an issue to be reviewed by the Board. The Board is required to make an expedited review determination in writing, either denying or granting the request, within 30 days after the date of receipt of the request, as defined in paragraph (1) of this section. The Board may also issue a determination on its own motion that it lacks authority to decide a question of law, regulations or HCFA Rulings.

(2) The Board must determine that the provider (including each provider in a group appeal) is entitled to a hearing under section 1878(a) of the Act before making the determination described in paragraph (b)(1) of this section. Thus, the provider must file (or have already filed) a written request for a Board hearing that meets the requirements in § 405.1841. The information and documentation required with respect to the filing of a request for a hearing is used by the Board to determine jurisdiction under section 1878(a) of the Act.

(3) A provider's request for an expedited review determination cannot be considered to be filed with the Board, nor can the 30-day time period during which the Board is required to make an expedited review determination begin, until such time as the Board accepts jurisdiction of the case.

(4) Proceedings conducted by the Board under an authority other than section 1878(a) of the Act and §§ 405.1835 through 405.1873 of this subpart are not hearings for purposes of this section and are not subject to the expedited Board proceedings set forth in this section. For example, proceedings concerning reimbursement for capital expenditures conducted under section 1122(f) of the Act and § 405.1890 of this subpart are not hearings for purposes of this section. (Section 1122(f) specifically bars any administrative or judicial review.)

(c) *''Own motion'' review.* If the Board is considering issuing a determination

on its own motion that it lacks the authority to decide a question of law, regulations, or HCFA Rulings, it will notify the provider and intermediary of its proposed determination and allow them a reasonable period of time to file evidence or arguments either to support or oppose the proposed determination.

(d) *Provider requests.* (1) If a provider seeks an expedited Board proceeding, it must—(i) File its appropriately documented request in writing with the Board; and

(ii) Send a copy of the request and documentation simultaneously to the intermediary.

(2) The request to the Board for an expedited review determination must—(i) Identify the issues and the controlling law, regulation or HCFA Ruling for which the Board is to make a determination;

(ii) Allege and demonstrate that there are no factual issues in dispute;

(iii) Contain an explanation of why the provider believes the Board cannot decide the legal issue or issues that are in dispute; and

(iv) Include all other information or details that support the request.

(3) If the information in the provider request is insufficient for the Board to determine whether it has the authority to decide an issue, the Board will request more information from the provider. Such a request will affect the 30-day time limit as provided in paragraph (i) of this section. If the provider does not send more information or sends inadequate information, the Board will determine that it has the authority to decide the issue and will begin the regular procedure for a hearing.

(e) *Intermediary participation.* (1) After receiving a copy of the provider's request for an expedited review determination, the intermediary may send comments to the Board on the provider's request and supporting documentation. The intermediary will send a copy of its comments to the provider simultaneously.

(2) If the intermediary's comments raise questions about the provider's request for expedited review, the Board may request additional information from the provider as provided in paragraph (d)(3) of this section.

(f) *Criteria for a Board determination.* The Board will review all documentation forwarded by the provider and the intermediary relevant to the request for a Board determination concerning the Board's authority to decide an issue. In its review, the Board will consider—

(1) The controlling facts in the case;

(2) The applicability of law, regulations, or HCFA rulings;

(3) Whether there are factual issues for the Board to resolve; and

(4) Whether there are legal issues within the authority of the Board to decide.

(g) *Board determination.* (1) Within 30 days after the date of receipt (as defined in paragraph (i) of this section) of a provider's request and all necessary documentation the Board will issue a determination concerning its authority to decide the question of law, regulations, or HCFA Rulings relevant to the issues identified by the provider in its request.

(2) If there are factual or legal issues in dispute on an issue within the authority of the Board to decide, the Board will not make an expedited review determination on the particular issue but will proceed with a hearing. The Board has the authority to decide when two or more issues are sufficiently related to preclude separation for purposes of an expedited review determination on one or more of them and a hearing on the other or others.

(3) The Board will promptly notify the provider in writing of its determination and will send a copy of the determination to the intermediary.

(4) The Board's determination concerning its authority or its lack of a determination is not subject to the Secretary's review under §405.1875.

(h) *Effect of a Board decision.* (1) The Board's determination, issued on its own motion or at the request of a provider, that it lacks authority to decide a question of law, regulations or HCFA Rulings is a final decision permitting a provider to seek judicial review with respect to the matter or matters in controversy contained in the determination, within 60 days of the date of the Board's determination.

(2) After the Board has determined that it does not have the authority to decide an issue, the provider will not be granted a hearing on the same issue.

(3) If the Board fails to issue an expedited review determination within 30 days of the date of receipt of a complete request (as determined under paragraph (i) of this section), the provider may, within 60 days from the end of that period, seek judicial review of the matters for which it requested the Board's determination.

(4) If the Board fails to make an expedited review determination within the required 30 days, it will begin regular hearing procedures as though it has the authority to decide the issue.

(5) If the provider seeks judicial review because the Board fails to make a determination as provided in paragraph (g)(1) of this section, it should notify the Board at the time it files for judicial review. The Board will not hold a hearing, even if one has been scheduled, on the matter or matters for which the provider is seeking judicial review.

(6) The Board's determination does not affect the right of the provider to a Board hearing for issues for which the provider did not request expedited review, or for which the Board determines it does have the authority to decide, or for which the Board did not make a determination and the provider did not request judicial review.

(i) *Date of receipt.* For purposes of this section, the date of receipt of the provider's request is the later of—

(1) The actual date of receipt by the Board of the information required under paragraph (d)(2) of this section, or of additional information requested by the Board under paragraph (d)(3) of this section, whichever the Board receives later; or

(2) The date indicated on the Board's written notification to the provider that the Board has accepted jurisdiction of the case.

(j) *Examples.* Below are examples showing when a provider may expect to receive an expedited review determination, in relation to various circumstances affecting its request for the determination.

(1) The provider requests a hearing and expedited review at or about the same time. If all information is complete, the Board could send notification that it has accepted jurisdiction of the case and the expedited review determination simultaneously.

(2) The provider requests both a hearing and an expedited review determination, and supplies complete information. The Board accepts jurisdiction but, for example, because of the complexity of the case, the Board makes its expedited review determination within 30 days after it has accepted jurisdiction.

(3) The provider requests both a hearing and an expedited review determination, but the request for a hearing does not contain enough information for the Board to determine jurisdiction. The Board would request more information to determine jurisdiction and would make its expedited review determination within 30 days after it has accepted jurisdiction.

(4) The provider requests both a hearing and an expedited review determination, but does not send enough information for the Board to make an expedited review determination. Assuming the Board accepts jurisdiction, the Board would request more information about the request for expedited review and make its determination within 30 days after it receives the additional information.

(5) The provider requests an expedited review determination after the Board has accepted jurisdiction. The Board would make its determination within 30 days after receipt of an appropriately documented request for an expedited review determination.

[47 FR 31690, July 22, 1982, as amended at 48 FR 22925, May 23, 1983]

§ 405.1843 Parties to Board hearing.

(a) The parties to the Board hearing shall be the provider, the intermediary (including the Health Care Financing Administration when acting directly as intermediary) that rendered the determination being appealed (see § 405.1833), and any other entity found by the intermediary to be a related organization of such provider.

(b) Except as provided in paragraph (a), neither the Secretary nor the Health Care Financing Administration may be made a party to the hearing.

However, the Board may call as a witness any employee or officer of the Department of Health and Human Services having personal knowledge of the facts and the issues in controversy in a hearing pending before the Board and may call as a consultant to the Board in connection with any such hearing any individual designated by the Secretary for such purpose. (See § 405.1863.)

§ 405.1845 Composition of Board.

(a) The Board will consist of five members appointed by the Secretary. All shall be knowledgeable in the field of cost reimbursement. At least one shall be a certified public accountant. Two Board members shall be representative of providers of services.

(b) The term of office for Board members shall be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office. No member shall serve more than two consecutive 3-year terms of office. The Secretary shall have the authority to terminate a Board member's term of office for good cause.

(c) One member of the Board shall be designated by the Secretary as Chairman thereof and shall coordinate and direct the administrative activities of the Board, and shall have such other authority which may be granted to him by the Board.

(d) A quorum shall be required for the rendering of Board decisions. Three members, at least one of whom is representative of providers of services, shall be required to constitute a quorum. The Chairman of the Board, with approval of the provider, may designate one or more Board members to conduct any hearing and to prepare a recommended decision (where less than a quorum conducts the hearing). (See § 405.1869.)

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall mail written notice thereof to the parties at their last known addresses, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that reasonable written notice is given to the parties.

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Health Care Financing Administration, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the mailing of notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

§ 405.1853 Prehearing discovery and other proceedings prior to the Board hearing.

(a) Upon notification that a request for Board hearing has been filed, the intermediary shall forthwith review

the materials submitted by the provider in accordance with § 405.1841. Simultaneously, the intermediary shall review the information which formed the basis for its determination of the amount of program reimbursement. Based on the findings of such review, the intermediary shall expeditiously attempt to join with the provider in written stipulations setting forth the issues that said review has resolved and designating the issues that remain for Board resolution. Having obtained such stipulations and being satisfied that no further agreements can be negotiated, the intermediary shall ensure that all available documentary evidence in support of each party's position is part of the record. Such evidence will ordinarily include a position paper from the provider, a position paper from the intermediary, and any documents which support the issues addressed in the stipulations. These materials, in addition to all relevant documents which formed the basis for its determination of the amount of program reimbursement, shall be forwarded to the Board within 60 days after the date of the provider's request for Board review.

(b) Prehearing discovery shall be permitted upon timely request of a party. To be timely, a request for discovery and inspection shall be made before the beginning of the hearing. A reasonable time for inspection and reproduction of documents shall be provided by order of the Board. The Board's order on all discovery matters shall be final.

(c) If, in the discretion of the Board, the purpose of defining the issues more clearly would be served, the Board may schedule a prehearing conference. For this purpose, a single member of the Board may be appointed to act for the Board with respect to prehearing activities.

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

When reasonably necessary for the full presentation of a case, the Board may, either upon its own motion or upon the request of a party, issue subpoenas for the attendance and testimony of witnesses and for the production of books, records, correspondence, papers, or other documents which are relevant and material to any matter in issue at the hearing. Parties who desire the issuance of a subpoena shall, not less than 10 days prior to the time fixed for the hearing, file with the Board a written request therefor, designating the witnesses or documents to be produced, and describing the address, or location thereof with sufficient particularity to permit such witnesses or documents to be found. The request for a subpoena shall state the pertinent facts which the party expects to establish by such witnesses or documents and whether such facts could be established by other evidence without the use of a subpoena. Subpoenas, as provided for above, shall be issued in the name of the Board, and the Health Care Financing Administration shall assume the cost of the issuance and the fees and mileage of any witness so subpoenaed, as provided in section 205(d) of the Act, 42 U.S.C. 405(d).

§ 405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§ 405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made

available to all parties and to the Health Care Financing Administration.

§ 405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Health Care Financing Administration.

§ 405.1865 Record of Board hearing.

A complete record of the proceedings at the hearing shall be made and transcribed in all cases. It shall be made available to the parties upon request. The record will not be closed until a decision has been issued.

§ 405.1867 Sources of Board's authority.

In exercising its authority to conduct the hearings described herein, the Board must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as HCFA Rulings issued under the authority of the Administrator of the Health Care Financing Administration (see § 401.108 of this subchapter). The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by HCFA.

[48 FR 22925, May 23, 1983]

§ 405.1869 Scope of Board's decision-making authority.

The Board shall have the power to affirm, modify, or reverse a determination of an intermediary with respect to a cost report and to make any other modifications on matters covered by such cost report (including modifications adverse to the provider or other parties) even though such matters were not considered in the intermediary's determination. The opinion of the majority of those Board members deciding the case will constitute the Board's decision.

§ 405.1871 Board hearing decision and notice.

(a) The Board shall, as soon as practicable after the conclusion of its hearing, render a written decision based upon the record made at such hearing, the record established in support of the determination of the intermediary (see § 405.1803), and such other evidence as may be obtained or received by the Board. Such Board decision shall be supported by substantial evidence when the record of the Board hearing is viewed as a whole and shall cite applicable law, regulations, and HCFA Rulings. A copy of the decision shall be mailed to all parties to the hearing at their last known addresses and, at the same time, to the Administrator and HCFA.

(b) The decision of the Board provided for in paragraph (a) of this section shall be final and binding upon all parties to the hearing before the Board unless it is reviewed by the Secretary in accordance with § 405.1875, or revised in accordance with § 405.1885.

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 48 FR 45773, Oct. 7, 1983]

§ 405.1873 Board's jurisdiction.

(a) *Board decides jurisdiction.* The Board decides questions relating to its jurisdiction to grant a hearing, including (1) the timeliness of an intermediary determination (see § 405.1835(c)), and (2) the right of a provider to a hearing before the Board when the amount in controversy is in issue (see §§ 405.1835(a)(3) and 405.1837).

(b) *Matters not subject to board review.* (1) The determination of a fiscal intermediary that no payment may be made under title XVIII of the Act for any expenses incurred for items and services furnished to an individual because such items and services are excluded from coverage pursuant to section 1862 of the Act, 42 U.S.C. 1395y (see subpart C of this part), may not be reviewed by the Board. (Such determination shall be reviewed only in accordance with the applicable provisions of subpart G or H of this part.)

(2) The Board may not review certain matters affecting payments to hospitals under the prospective payment system as provided in § 405.1804.

[48 FR 39836, Sept. 1, 1983]

§ 405.1875 Administrator's review.

(a) *General rule.* (1) Except for a Board determination under § 405.1842 that it lacks the authority to decide an issue, the Administrator, at his or her discretion, may review any final decision of the Board, including a decision under § 405.1873 about the Board's jurisdiction to grant a hearing. The Administrator may exercise this discretion on his or her own motion, in response to a request from a party to a Board hearing or in response to a request from HCFA.

(2) The Office of the Attorney Advisory will examine the Board's decisions, the requests made by a party or HCFA and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to exercise this review authority.

(b) *Request for review.* A party or HCFA requesting the Administrator to review a Board decision must file a written request with the Administrator within 15 days of the receipt of the Board decision.

(c) *Criteria for deciding whether to review.* In deciding whether to review a Board decision, either on his or her own motion or in response to a request from a party to the hearing or HCFA, the Administrator will normally consider whether it appears that:

(1) The Board made an erroneous interpretation of law, regulation or HCFA Ruling;

(2) The Board's decision is not supported by substantial evidence; or

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a HCFA Ruling or other directive needed to clarify a statutory or regulatory provision;

(4) The Board has incorrectly assumed or denied jurisdiction or extended its authority to a degree not provided for by statute, regulation or HCFA Ruling; and

(5) The decision of the Board requires clarification, amplification, or an alternative legal basis for the decision.

(d) *Decision to review.* (1) Whether or not a party or HCFA has requested review, the Administrator will promptly notify the parties and HCFA whether he or she has decided to review a decision of the Board and, if so, will indicate the particular issues he or she will consider.

(2) The Administrator may decline to review a case or any issue in a case even if a party has filed a written request for review under paragraph (b) of this section.

(e) *Written submissions.* (1) Within 15 days of receipt of a notice that the Administrator has decided to review a Board decision, a party or HCFA may submit to the Administrator, in writing:

(i) Proposed findings and conclusions;

(ii) Supporting views or exceptions to the Board decision;

(iii) Supporting reasons for the exceptions and proposed findings; and

(iv) A rebuttal of the other party's request for review or other submissions already filed with the Administrator.

(2) These submissions shall be limited to issues the Administrator has decided to review and confined to the record of the Board hearing.

(3) A party or HCFA, within 15 days of receipt of a notice that the Administrator has decided to review a decision, may also request that the decision be remanded and state reasons for doing so. Reasons for a request to remand may include new, substantial evidence concerning—

(i) Issues presented to the Board; and

(ii) New issues that have arisen since the case was presented to the Board.

(4) A copy of any written submission made under this paragraph shall be sent simultaneously to each other party to the Board hearing and to HCFA, if HCFA has previously—

(i) Requested that the Administrator review a Board decision or filed a written submission in response to a party's request for review.

(ii) Responded to a party's request for review; or

(iii) Submitted material after the Administrator has announced that he or she will review a Board decision.

(f) *Ex parte communications prohibited.* All communications from any of the parties or HCFA about a Board decision being reviewed by the Administrator must be in writing and must contain a certification that copies have been served on the parties and HCFA, as appropriate. The Administrator will

not consider any communication that does not meet these requirements or is not submitted within the required time limits.

(g) *Administrator's decision.* (1) If the Administrator has notified the parties and HCFA that he or she has decided to review a Board decision, the Administrator will affirm, reverse, modify or remand the case.

(2) The Administrator will make this decision within 60 days after the provider received notification of the Board decision and will promptly mail a copy of the decision to each party and to HCFA.

(3) Any decision other than to remand will be confined to—

(i) The record of the Board, as forwarded by the Board;

(ii) Any materials submitted under paragraphs (b) or (e) of this section; and

(iii) Generally known facts that are not subject to reasonable dispute.

(4) The Administrator may rely on prior decisions of the Board, the Administrator and the courts, and other applicable law, whether or not cited by the parties and HCFA.

(h) *Remand.* (1) A remand to the Board by the Administrator vacates the Board's decision.

(2) The Administrator may direct the Board to take further action with respect to the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand—

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably could have been known;

(ii) Introduction of a favorable court case that was either not available in print at the time of the Board hearing or was decided after the Board hearing;

(iii) Change of a party's representation before the Board;

(iv) Presentation of an alternative legal basis concerning an issue in dispute; or

(v) Attempted retraction of a waiver of a right made before or at the Board hearing.

(3) After remand, the Board will take the action requested in the remand action and issue a new decision.

(4) The new decision will be final unless the Administrator reverses, affirms, modifies, or again remands the decision in accordance with the provisions of the section.

[48 FR 45773, Oct. 7, 1983]

§405.1877 Judicial review.

(a) *General rule.* Section 1878(f) of the Act permits a provider to obtain judicial review of a final decision of the Board, or of a reversal, affirmation, or modification by the Administrator of a Board decision, by filing a civil action pursuant to the Federal Rules of Civil Procedure within 60 days of the date on which the provider received notice of—

(1) A final decision by the Board; or

(2) Any reversal, affirmance, or modification by the Administrator.

The Board's decision is not final if the Administrator reverses, affirms or modifies the decision within 60 days of the date on which the provider received notice of the decision.

(b) *Administrator declines to review a Board decision.* If the Administrator declines to review a Board decision, the provider must file its appeal within 60 days of receipt of the decision of the Board.

(c) *Administrator does not act after reviewing a Board decision.* If the Administrator notifies the parties that he or she has decided to review a Board decision and then does not make a decision within the 60 days allotted for his or her review, this subsequent inaction constitutes an affirmance allowing a provider an additional 60 days in which to file for judicial review, beginning with the date the Administrator's time expires for taking action under §405.1875(g)(2).

(d) *Matters not subject to judicial review.* Certain matters affecting payments to hospital under the prospective payment system are not subject to judicial review, as provided in section 1886(d)(7) of the Act and §405.1804.

(e) *Group appeals.* Any action under this section by providers that are under common ownership or control (see §413.17 of this chapter) must be brought by the providers as a group

with respect to any matter involving an issue common to the providers.

(f) *Venue for appeals.* An action for judicial review must be brought in the District Court of the United States for the judicial district in which the provider is located (or, effective April 20, 1983, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia. Effective April 20, 1983, any action for judicial review by providers under common ownership or control (§ 413.17 of this chapter), must be brought by such providers as a group with respect to any matter involving an issue common to the providers.

(g) *Service of process.* Process must be served as described under 45 CFR part 4.

[48 FR 39836, Sept. 1, 1983, as amended at 48 FR 45774, Oct. 7, 1983; 51 FR 34793, Sept. 30, 1986]

§ 405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§ 405.1819 and 405.1851.

§ 405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for an intermediary hearing or a Board hearing made in accordance with §§ 405.1811, 405.1835, or 405.1837 to the same extent as the party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a determination or decision.

(a) A determination of an intermediary, a decision by a hearing officer or panel of hearing officers, a decision by the Board, or a decision of the Secretary may be reopened with respect to findings on matters at issue in such determination or decision, by such intermediary officer or panel of hearing officers, Board, or Secretary, as the case may be, either on motion of such intermediary officer or panel of hearing officers, Board, or Secretary, or on the motion of the provider affected by such determination or decision to revise any matter in issue at any such proceedings. Any such request to reopen must be made within 3 years of the date of the notice of the intermediary or Board hearing decision, or where there has been no such decision, any such request to reopen must be made within 3 years of the date of notice of the intermediary determination. No such determination or decision may be reopened after such 3-year period except as provided in paragraphs (d) and (e) of this section.

(b) A determination or a hearing decision rendered by the intermediary shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the Health Care Financing Administration notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Health Care Financing Administration in accordance with the Secretary's agreement with the intermediary.

(c) Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision.

(d) Notwithstanding the provisions of paragraph (a) of this section, an intermediary determination or hearing decision, a decision of the Board, or a decision of the Secretary shall be reopened and revised at any time if it is established that such determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(e) Paragraphs (a) and (b) of this section apply to determinations on cost

reporting periods ending on or after December 31, 1971. (See §405.1801(c).) However, the 3-year period described shall also apply to determinations with respect to cost reporting periods ending prior to December 31, 1971, but only if the reopening action was undertaken after May 27, 1972 (the effective date of regulations which, prior to the publication of this subpart R, governed the reopening of such determinations).

§405.1887 Notice of reopening.

(a) All parties to any reopening described above shall be given written notice of the reopening. When such reopening results in any revision in the prior decision notice of said revision or revisions will be mailed to the parties with a complete explanation of the basis for the revision or revisions. Notices of reopenings by the Board shall also be sent to the Secretary.

(b) In any such reopening, the parties to the prior decision shall be allowed a reasonable period of time in which to present any additional evidence or argument in support of their position.

§405.1889 Effect of a revision.

Where a revision is made in a determination or decision on the amount of program reimbursement after such determination or decision has been reopened as provided in §405.1885, such revision shall be considered a separate and distinct determination or decision to which the provisions of §§405.1811, 405.1835, 405.1875 and 405.1877 are applicable. (See §405.1801(c) for applicable effective dates.)

Subparts S–T—[Reserved]

Subpart U—Conditions for Coverage of Suppliers of End–Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in §405.2101, and general definitions are contained in §405.2102. The provisions of §§405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

(a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;

(b) To encourage proper distribution and effective utlization of ESRD treatment resources while maintaining or improving the quality of care;

(c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and

(d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of ''ESRD service''). Such facilities are:

(a) *Renal Transplantation Center.* A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Transplantation service.* A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service*—(1) *Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or

home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through ''agreements'' or ''arrangements'').

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (*MCE*). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in § 485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer.* A person who:

(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American

Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.* A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or

(2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process;

(3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or

(2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;

(3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) *Social worker.* A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990]

§ 405.2110 Designation of ESRD networks.

HCFA designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* HCFA will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

HCFA will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation

and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to HCFA an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or HCFA, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§405.2114 [Reserved]

§405.2120 Minimum utilization rates: general.

Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) authorizes the Secretary to limit payment for ESRD care to those facilities that meet the requirements that the Secretary may prescribe, including minimum utilization rates for covered transplantations. The minimum utilization rates, which are explained and specified in §§405.2121 through 405.2130, may be changed from time to time in accordance with program experience. Changes will be published as amendments to these regulations.

[55 FR 23440, June 8, 1990]

§405.2121 Basis for determining minimum utilization rates.

In developing minimum utilization rates, the Secretary takes into account the performance of ESRD facilities, the

availability of care, the quality of care, and the efficient utilization of equipment and personnel, based on the following evidence:

(a) Information on the geographic distribution of ESRD patients and facilities;

(b) Information on quality of care; and

(c) Information on operational and management efficiency.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2122 Types and duration of classification according to utilization rates.

A renal transplantation center that meets all the other conditions for coverage of ESRD services will be classified according to its utilization rate(s) as follows: Unconditional status, conditional status, exception status, or not eligible for reimbursement for that ESRD service. Such classification will be based on previously reported utilization data (see § 405.2124, except as specified in paragraph (a) of this section), and will be effective until notification of subsequent classification occurs. (See § 405.2123 for reporting requirements; § 405.2124 for method of calculating rates: § 405.2130 for specific standards.)

(a) *Initial classification.* (1) A renal transplantation center that has not previously participated in the ESRD program will be granted conditional status if it submits a written plan, detailing how it will achieve the utilization rates for conditional status by the end of the second calendar year of its operation under the ESRD program, and the rates required for unconditional status by the end of its fourth calendar year of operation.

(2) The renal transplantation center's performance will be evaluated at the end of the first calendar year to ascertain whether it is properly implementing the plan.

(b) *Exception status.* (1) A renal transplantation center that does not meet the minimum utilization rate for unconditional or conditional status may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage under this subpart;

(ii) It is unable to meet the minimum utilization rate because it lacks a sufficient number of patients and is located in an area without a sufficient population base to support a center or facility which would meet the rate; and

(iii) Its absence would adversely affect the achievement of ESRD program objectives.

(2) A hospital that furnishes renal transplantation services primarily to pediatric patients and is approved as a renal dialysis center under this subpart, but does not meet the utilization standards prescribed in § 405.2130(a), may be approved by the Secretary for a time limited exception status if:

(i) It meets all other conditions for coverage as a renal transplantation center;

(ii) The surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2102) who is also performing renal transplantation surgery at an approved renal transplantation center that is primarily oriented to adult nephrology;

(iii) It has an agreement, with the other hospital serviced by the surgeon, for sharing limited resources that are needed for kidney transplantation; and

(iv) There are pediatric patients who need the surgery and who cannot obtain it from any other hospital located within a reasonable distance.

[43 FR 48951, Oct. 19, 1978, as amended at 45 FR 58124, Sept. 2, 1980; 51 FR 30362, Aug. 26, 1986; 55 FR 23440, June 8, 1990]

§ 405.2123 Reporting of utilization rates for classification.

Each hospital furnishing renal transplantation services must submit an annual report to HCFA on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding 2 calendar years.

[55 FR 23441, June 8, 1990]

§405.2124 Calculation of utilization rates for comparison with minimal utilization rate(s) and notification of status.

For purposes of classification the Secretary will use either the utilization rate for the preceding 12 months or the average utilization rate of the preceding 2 calendar years, whichever is higher. The Secretary will inform each ESRD facility and the network coordinating council of the network area in which the ESRD facility is located of the results of this classification.

§405.2130 Condition: Minimum utilization rates.

Unless a renal transplantation center is granted an exception under §405.2122(b), the center must meet the following minimum utilization rate(s) for unconditional or conditional status:

(a) Unconditional status: 15 or more transplants performed annually.

(b) Conditional status: 7 to 14 transplants performed annually.

[55 FR 23441, June 8, 1990]

§405.2131 Condition: Provider status: Renal transplantation center or renal dialysis center.

A renal transplantation center or a renal dialysis center (§405.2102(e) (1) or (2)) operated by a hospital may qualify for approval and be reimbursed under the ESRD program only if the hospital is otherwise an approved provider in the Medicare program.

§405.2132 [Reserved]

§405.2133 Condition: Furnishing data and information for ESRD program administration.

The ESRD facility, laboratory performing histocompatibility testing, and organ procurement organization furnishes data and information in the manner and at the intervals specified by the Secretary, pertaining to its ESRD patient care activities and costs, for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

§405.2134 Condition: Participation in network activities.

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

§405.2135 Condition: Compliance with Federal, State and local laws and regulations.

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

(1) Licensed pursuant to such law; or

(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

§405.2136 Condition: Governing body and management.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer

who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 per centum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see § 405.2137).

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) *Standard: chief executive officer.* The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contracts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) *Standard: personnel policies and procedures.* The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.

(e) *Standard: use of outside resources.* If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resource, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment

through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) *Standard: patient care policies.* The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement).

(ii) Admission and discharge policies (in relation to both in-facility care and home care).

(iii) Medical supervision and physician services.

(iv) Patient long term programs, patient care plans and methods of implementation.

(v) Care of patients in medical and other emergencies.

(vi) Pharmaceutical services.

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).

(viii) Administrative records.

(ix) Use and maintenance of the physical plant and equipment.

(x) Consultant qualifications, functions, and responsibilities.

(xi) The provision of home dialysis support services, if offered (see § 405.2163(e)).

(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physican director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physican-director provides medical guidance in such matters.

(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their nonworking hours.

(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan (see § 405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

(g) *Standard: medical supervision and emergency coverage.* The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medications, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge. Such plans are made with input from other professional personnel involved in the care of the patient.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) *Standard: medical staff.* The governing body of the ESRD facility designates a qualified physician (see § 405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written

policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2137 Condition: Patient long-term program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.* There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see §405.2161(b)(1) and §405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see §405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home–dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See §405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.

(vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.

(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]

§ 405.2138 Condition: Patients' rights and responsibilities.

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) *Standard: informed patients.* All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) *Standard: participation in planning.* All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) *Standard: respect and dignity.* All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) *Standard: confidentiality.* All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) *Standard: grievance mechanism.* All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes

in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 51 FR 30362, Aug. 26, 1986; 52 FR 36934, Oct. 2, 1987]

§405.2139 Condition: Medical records.

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) *Standard: medical record.* Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (see §405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in §405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) *Standard: protection of medical record information.* The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(c) *Standard: medical records supervisor.* A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

(d) *Standard: Completion of medical records and centralization of clinical information.* Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) *Standard: retention and preservation of records.* Medical records are retained for a period of time not less than that determined by the State statute governing records retention or

statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

(f) *Standard: location and facilities.* The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

(g) *Standard: transfer of medical information.* The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 52 FR 36934, Oct. 2, 1987]

§ 405.2140 Condition: Physical environment.

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(a) *Standard: building and equipment.* The physical structure in which ESRD services are furnished is constructed, equipped, and maintained to insure the safety of patients, staff, and the public.

(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.

(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients or personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.

(4) [Reserved]

(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in ''Hemodialysis Systems,'' second edition, which is incorporated by reference.

(ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2, Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

(iii) Incorporation by reference of the AAMI's ''Hemodialysis Systems,'' second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Hemodialysis Systems,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(b) *Standard: favorable environment for patients.* The facility is maintained and equipped to provide a functional sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and

[1] The publication entitled ''Hemodialysis Systems,'' second edition, 1992, is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

storage of reused items which conform to requirements for reuse in §405.2150.

(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accomodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency. There is sufficient space in units for safe storage of self-dialysis supplies.

(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.

(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.

(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see §405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.

(c) *Standard contamination prevention.* The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see §405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in §405.2150.

(d) *Standard: emergency preparedness.* Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specified role in case of an emergency.

(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.

(Secs. 1102, 1871, 1881(b), Social Security Act; 42 U.S.C. 1302, 1395hh, 1395rr(b))

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 43 FR 48952, Oct. 19, 1978; 45 FR 24839, Apr. 10, 1980; 52 FR 36934, Oct. 2, 1987; 60 FR 48043, Sept. 18, 1995]

§405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies.

An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.

(a) *Standard: Hemodialyzers.* If the ESRD facility reuses hemodialyzers, it conforms to the following:

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI (''Reuse of Hemodialyzers,'' second edition). Incorporation by reference of the AAMI's ''Reuse of Hemodialyzers,'' second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] If any changes in ''Reuse of Hemodialyzers,'' second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for ''single use only'';

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995]

§ 405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see § 405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

[1] The publication entitled ''Reuse of Hemodialyzers,'' second edition, 1993, is available for inspection at the HCFA Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244–1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

§ 405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services*—(1) *Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in

accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

(1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;

(2) Consultation for the patient with a qualified social worker and a qualified dietitian;

(3) A recordkeeping system which assures continuity of care;

(4) Installation and maintenance of equipment;

(5) Testing and appropriate treatment of the water; and

(6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who

prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.* The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug ''on hand'' at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§405.2130 through 405.2164, with the exception of §§405.2134, and 405.2137 that relate to participation in the network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under §405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§405.2102) or a qualified physician-director (§405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by HCFA as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff;

if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(d) *Standard: Laboratory services:* (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) *Standard: Organ procurement.* A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify HCFA in writing within 30 days of the termination of the agreement.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988; 57 FR 7134, Feb. 28, 1992; 59 FR 46514, Sept. 8, 1994]

§ 405.2180 Termination of Medicare coverage.

(a) Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this subpart U will result in termination of Medicare coverage of the services furnished by that supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required by § 405.2134, coverage may be reinstated when HCFA determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in this subpart, coverage will not be reinstated until HCFA finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

[53 FR 36277, Sept. 19, 1988]

§ 405.2181 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* HCFA may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if HCFA finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass its geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that HCFA may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of sanction.* An alternative sanction remains in effect until HCFA finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

[53 FR 36277, Sept. 19, 1988]

§405.2182 Notice of sanction and appeal rights: Termination of coverage.

(a) *Notice of sanction.* HCFA gives the supplier and the general public notice of sanction and of the effective date of the sanction. The effective date of the sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

[53 FR 36277, Sept. 19, 1988]

§405.2184 Notice of appeal rights: Alternative sanctions.

If HCFA proposes to apply a sanction specified in §405.2181(b), the following rules apply:

(a) HCFA gives the facility notice of the proposed sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, HCFA provides an informal hearing by a HCFA official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, HCFA provides the facility and the public, at least 30 days before the effective date of the sanction, with a written notice that specifies the effective date and the reasons for the sanction.

[53 FR 36277, Sept. 19, 1988]

Subparts V–W—[Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first $100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with HCFA to meet Medicare program requirements under §§ 405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by HCFA to meet the requirements for receiving such a grant;

(3) Was treated by HCFA, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

HCFA stands for Health Care Financing Administration.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a

full-time basis, that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.

(2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)

(3) A resident (including residents as defined in §415.152 of this chapter who meet the requirements in §415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic means a facility that:

(1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and

(2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See §405.2402.)

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996]

§405.2402 Basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services.* If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic.* If the rural health clinic wishes to participate in the program, it must:

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement.* The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) *Appeal rights.* If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with part 498 of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§405.2403 Content and terms of the agreement with the Secretary.

(a) Under the agreement, the rural health clinic agrees to the following:

(1) *Maintaining compliance with conditions.* The clinic agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to HCFA any failure to do so.

(2) *Charges to beneficiaries.* The clinic agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to

have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2404 Terminations of agreements.

(a) *Termination by rural health clinic.* (1) *Notice to Secretary.* If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) *Termination by the Secretary.* (1) *Cause for termination.* The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary will give notice of termination to the rural health clinic at least 15 days before the effective date stated in the notice.

(3) *Appeal by the rural health clinic.* A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not file another agreement to participate

in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for rural health clinic services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the Federally qualified health center benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for a coinsurance amount which cannot exceed 20 percent of the clinic's reasonable customary charge for the covered service; and

(2)(i) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the rural health clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

(ii) For any one item or service furnished by a Federally qualified health center, the coinsurance liability may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service.

[57 FR 24976, June 12, 1992]

§405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this subpart are:

(1) The physicians' services specified in §405.2412;

(2) Services and supplies furnished as an incident to a physician's professional service;

(3) The nurse practitioner or physician assistant services specified in §405.2414;

(4) Services and supplies furnished as an incident to a nurse practitioner's or physician assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

§405.2412 Physicians' services.

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

§405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Furnished under the direct, personal supervision of a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§405.2414 Nurse practitioner and physician assistant services.

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

(2) Furnished under the medical supervision of a physician;

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;

(4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the

State in which the service is rendered; and

(5) They would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants, nurse midwives or specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;

(4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if:

(1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

(i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and

(ii) Signed by the nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or long term care facility.

§405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, HCFA enters into an agreement with an entity when—

(i) PHS recommends that the entity qualifies as a Federally qualified health center;

(ii) The Federally qualified health center assures HCFA that it meets the Federally qualified health center requirements specified in this subpart and part 491, as described in §405.2434(a); and

(iii) The FQHC terminates other provider agreements, unless the FQHC assures HCFA that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) HCFA sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, HCFA sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to HCFA.

(4) If HCFA accepts the agreement filed by the Federally qualified health center, HCFA returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see §489.11), as determined under §405.2434.

(b) *Recommendations by PHS about Federally qualified health centers.* (1) An entity must—

(i) Meet the applicable requirements of the PHS Act, as specified in §405.2401(b); and

(ii) Be recommended by PHS to HCFA as a Federally qualified health center.

(2) The PHS notifies HCFA of entities that meet the requirements specified in §405.2401(b).

(c) *Provider-based and freestanding Federally qualified health centers.* The requirements and benefits under Medicare for provider-based or freestanding Federally qualified health centers are the same, except that payment methodologies differ, as described in §405.2462.

(d) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when HCFA fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2434 Content and terms of the agreement.

Under the agreement, the Federally qualified health center must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The Federally qualified health center must agree to maintain compliance with the Federally qualified health center requirements set forth in this subpart and part 491, except that the provisions of §491.3 do not apply.

(2) Centers must promptly report to HCFA any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* (1) Except as specified in paragraph (b)(2) of this section, the effective date of the agreement is the date HCFA accepts the signed agreement, which assures that all Federal requirements are met.

(2) For facilities that met all requirements on October 1, 1991, the effective

date of the agreement can be October 1, 1991.

(c) *Charges to beneficiaries.* (1) The beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the Federally qualified health center for the covered services. There is no coinsurance for a second or third opinion obtained in accordance with section 1164 of the Act or for pneumococcal vaccine and its administration.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The Federally qualified health center agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any Federally qualified health center services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the Federally qualified health center had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The Federally qualified health center may charge the beneficiary for items and services that are not Federally qualified health center services. However, if the item or service is covered under Part B of Medicare, and the Federally qualified health center agrees to receive Part B payment under the assignment method, the Federally qualified health center may not charge the beneficiary more than 20 percent of the Part B payment.

(d) *Refunds to beneficiaries.* (1) The Federally qualified health center must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, ''money incorrectly collected'' means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the Federally qualified health center believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the Federally qualified health center's agreement with HCFA was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The Federally qualified health center must agree to accept Medicare beneficiaries for care and treatment.

(2) The Federally qualified health center may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the Federally qualified health center. Failure to comply with this requirement is a cause for termination of the Federally qualified health center's agreement with HCFA in accordance with § 405.2436(d).

(3) If the Federally qualified health center does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

§ 405.2436 Termination of agreement.

(a) *Termination by Federally qualified health center.* The Federally qualified health center may terminate its agreement by—

(1) Filing with HCFA a written notice stating its intention to terminate the agreement; and

(2) Notifying HCFA of the date on which the Federally qualified health center requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a Federally qualified health center's notice of intention to terminate the agreement, HCFA will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the Federally qualified health center in its notice of intention to terminate, if that date is acceptable to HCFA; or

(ii) Except as specified in paragraph (2) of this section, a date set by HCFA, which is no later than 6 months after the date HCFA receives the Federally

qualified health center's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following HCFA's receipt of the Federally qualified health center's notice of intention to terminate if HCFA determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of Federally qualified health center services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a Federally qualified health center.

(c) *Termination by HCFA.* (1) HCFA may terminate an agreement with a Federally qualified health center if it finds that the Federally qualified health center—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by HCFA.* HCFA will notify the Federally qualified health center in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A Federally qualified health center may appeal HCFA's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a Federally qualified health center's agreement is terminated whether by the Federally qualified health center or HCFA, payment will not be available for Federally qualified health center services furnished on or after the effective date of termination.

§ 405.2440 Conditions for reinstatement after termination by HCFA.

When HCFA has terminated an agreement with a Federally qualified health center, HCFA will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless HCFA—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

§ 405.2442 Notice to the public.

(a) When the Federally qualified health center voluntarily terminates the agreement and an effective date is set for the termination, the Federally qualified health center must notify the public prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set, through publication in at least one newspaper in general circulation in the area serviced by the Federally qualified health center of the—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When HCFA terminates the agreement, HCFA will notify the public through publication in at least one newspaper in general circulation in the Federally qualified health center's service area.

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*—(1) *Incorporation.* The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger.* The merger of the center corporation into another corporation, or the consolidation of two or more corporations, one of which is the center corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the center corporation does not constitute change of ownership.)

(3) *Leasing.* The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to HCFA.* A center which is contemplating or negotiating change of ownership must notify HCFA.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing center is automatically assigned to the new

owner if it continues to meet the conditions to be a Federally qualified health center.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms *rural health clinic* and *clinic* when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and clinical social worker services specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or clinical social worker services, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

(c) Federally qualified health center services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility or other institution used as a patient's home.

(d) Federally qualified health center services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A center is required to provide as preventive primary health services under section 329, 330, and 340 of the Public Health Service Act;

(2) Are furnished by or under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, clinical psychologist, clinical social worker, or a physician;

(3) In the case of a service, are furnished by a member of the center's health care staff who is an employee of the center or by a physician under arrangements with the center; and

(4) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by Federally qualified health centers are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diptheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a Federally qualified health center service, but may be provided at a Federally qualified health center if the center meets the requirements applicable to that service specified in §410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or clinical social worker professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist or clinical social worker who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker or clinical psychologist who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in §491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists or clinical social workers are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) Services and supplies incident to a clinical psychologist's or clinical social worker's services are reimbursable under this subpart if the service or supply is—

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the Federally qualified health center's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist or clinical social worker;

(4) Furnished under the direct, personal supervision of a clinical psychologist, clinical social worker or physician; and

(5) In the case of a service, furnished by a member of the center's health care staff who is an employee of the center.

(b) The direct personal supervision requirement in paragraph (a)(4) of this section is met only if the clinical psychologist or clinical social worker is permitted to supervise such services under the written policies governing the Federally qualified health center.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by rural health clinics and Federally qualified health centers, except that preventive primary services, as defined in §405.2448, are covered in Federally qualified health centers and not excluded by the provisions of section 1862(a) of the Act.

§ 405.2462 Payment for rural health clinic and Federally qualified health center services.

(a) *Payment to provider-based rural health clinics and Federally qualified health centers.* A rural health clinic or Federally qualified health center is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if:

(1) The clinic or center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e., a provider of services); and

(2) The clinic or center is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent rural health clinics and freestanding Federally qualified health centers.* (1) All other clinics and centers will be paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate will be determined by the intermediary, in accordance with this subpart and general instructions issued by HCFA.

(2) The amount payable by the intermediary for a visit will be determined in accordance with paragraph (b)(3) and (4) of this section.

(3) *Federally qualified health centers.* For Federally qualified health center visits, Medicare will pay 80 percent of the all-inclusive rate since no deductible is applicable to Federally qualified health center services.

(4) *Rural health clinics.* (i) If the deductible has been fully met by the beneficiary prior to the rural health clinic visit, Medicare pays 80 percent of the all-inclusive rate.

(ii) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the clinic's reasonable customary charge for the services that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic;

(B) Equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(5) To receive payment, the clinic or center must follow the payment procedures specified in section 410.165 of this chapter.

(6) Payment for treatment of mental psychoneurotic or personality disorders is subject to the limitations on payment in § 410.155(c).

§ 405.2463 What constitutes a visit.

(a) *Visit.* (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or clinical social worker.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) *Payment.* (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) *Medical visit.* For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(c) *Other health visit.* For purposes of paragraph (a)(3) of this section, an other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, clinical social worker, or other health professional for mental health services.

[61 FR 14657, Apr. 3, 1996]

§ 405.2464 All-inclusive rate.

(a) *Determination of rate.* (1) An all-inclusive rate is determined by the intermediary at the beginning of the reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by

estimated total visits for rural health clinic or Federally qualified health center services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) *Adjustment of rate.* (1) The intermediary, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits for rural health clinic or Federally qualified health center services and adjusts the rate if:

(i) There is a significant change in the utilization of clinic or center services;

(ii) Actual allowable costs vary materially from the clinic or center's allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic or center may request the intermediary to review the rate to determine whether adjustment is required.

§ 405.2466 Annual reconciliation.

(a) *General.* Payments made to a rural health clinic or a Federally qualified health center during a reporting period are subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation.* (1) The total reimbursement amount due the clinic or center for covered services furnished to Medicare beneficiaries is based on the report specified in § 405.2470(c)(2) and is calculated by the intermediary as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic or Federally qualified health center services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic or Federally qualified health center services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic or Federally qualified health center services by beneficiaries.

(iii) For rural health clinics, the total reimbursement due the clinic is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to rural health clinic services from the cost of these services. The reimbursement computation for Federally qualified health centers does not include a reduction related to the deductible because Federally qualified health center services are not subject to a deductible.

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the clinic or center for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The intermediary sends written notice to the clinic or center:

(1) Setting forth its determination of the total reimbursement amount due the clinic or center for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the clinic or center of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the clinic or center exceeds the payments made for the reporting period, the intermediary makes a lump-sum payment to the clinic or center to bring total payments into agreement with total reimbursement due the clinic or center.

(2) *Overpayments.* If the total payments made to a clinic or center for the reporting period exceed the total reimbursement due the clinic or center for the period, the intermediary arranges with the clinic or center for repayment through a lump-sum refund, or, if that poses a hardship for the clinic or center, through offset against

subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the intermediary if the intermediary is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the intermediary applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical rural health clinic and Federally qualified health center costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and clinical social worker who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or clinical social worker.

(4) Overhead costs, including clinic or center administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the clinic or center.

(c) *Tests of reasonableness for rural health clinic cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by HCFA or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the clinic or center provides reasonable justification satisfactory to the intermediary.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and clinical social workers.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by HCFA, on the basis of costs estimated to be reasonable for the provision of such services.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996]

§ 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The rural health clinic or Federally qualified health center must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by HCFA, to allow the intermediary to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The intermediary may suspend reimbursement if it determines that the clinic or center does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the clinic or center demonstrates to the intermediary's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the clinic or center must submit an estimate of budgeted costs and visits for rural health clinic or Federally qualified health center services for the reporting period, in the form and detail required by HCFA, and such other information as HCFA may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the clinic or center must submit, in such form and detail as may be required by HCFA, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic or Federally qualified health center services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services or Federally qualified health center services for the succeeding reporting period and such other information as HCFA may require to establish the payment rate.

(3) *Late reports.* If the clinic or center does not submit an adequate annual report on time, the intermediary may reduce or suspend payments to preclude excess payment to the clinic or center.

(4) *Inadequate reports.* If the clinic or center does not furnish a report or furnishes a report that is inadequate for the intermediary to make a determination of program payment, HCFA may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the clinic or center, the intermediary may, with HCFA's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership.* The report from a clinic or center which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with an intermediary's determination denying a request for payment made on his or her behalf by a rural health clinic or Federally qualified health center; or

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992]

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

Subpart A—General Provisions

Sec.

Subpart B—Hospital Insurance Without Monthly Premiums